REDACTED DOCUMENTS RELATED TO DOCKET 7011

7027-Defendants' Memorandum of Law in Opposition to Plaintiffs' Request to Retake the Deposition of David Henry, M.D. Deposition of Henry David, M.D. – Filed Redacted

7028-Plaintiffs' Memorandum of Issues Regarding the Deposition of David Henry, M.D. - Filed Redacted

David Henry, M.D. Deposition Transcript Dated April 6, 2017 - Filed Redacted 7027-Defendants' Memorandum of Law in Opposition to Plaintiffs' Request to Retake the Deposition of David Henry, M.D. Deposition of Henry David, M.D. Filed Redacted

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14	IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF ARIZONA	
15		
16	DIDE D. INGELL D. L. L'121.	N. MD 15 02641 DHV DGG
17	IN RE: Bard IVC Filters Products Liability Litigation,	No. MD-15-02641-PHX-DGC
18		DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO
19	LISA HYDE, an individual,	PLAINTIFFS' REQUEST TO RETAKE THE DEPOSITION OF
20	Plaintiff,	DAVID HENRY, M.D.
21	v.	
22	C.R. BARD, INC., a New Jersey corporation and BARD PERIPHERAL	
23	VASCULAR, an Arizona corporation,	
24	Defendants.	
25		
26	Pursuant to Case Management Order	No. 26 (Doc. No. 6799), this Court requested
27	the parties to submit memoranda addressing	four issues relating to Plaintiffs' request to

retake the deposition of Dr. David Henry. Per the Court's request, Defendants

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respectfully submit this memorandum of law addressing each of the issues raised by the
Court as follows: (1) Federal Rule of Evidence 501 applies to the privilege asserted by
Dr. Henry's counsel; (2) Wisconsin law supplies the rule of decision regarding the
application of state privilege law under Rule 501; (3) Wisconsin law supports the
objections and instructions made by Dr. Henry's attorney; and (4) Dr. Henry's privilege-
based objections did not obstruct Plaintiffs' counsel from seeking required testimony
under the learned intermediary doctrine relevant to the issue of causation for failure-to-
warn claims.

INTRODUCTION

Dr. David Henry ("Dr. Henry") is a vascular and interventional radiologist licensed and practicing in the state of Wisconsin.

During the deposition, Dr. Henry's counsel objected to several questions posed by Plaintiffs' counsel and instructed Dr. Henry not to answer on the grounds of a privilege for un-retained experts recognized under Wisconsin law. See the Depo. of David Henry, M.D. (filed as a Sealed Lodged document at DKT 7012). Plaintiffs' counsel now seeks the Court's leave to re-depose Dr. Henry for the purpose of having Dr. Henry provide answers to the questions objected to at the deposition. Pursuant to Fed. R. Evid. 501 and applicable choice of law principles, however, Wisconsin law applies to and supports the invocation of privilege during Dr. Henry's deposition. Consequently, Plaintiffs' request to retake the deposition of Dr. Henry should be denied.

ARGUMENT

I. Federal Rule of Evidence 501 Applies to the Privilege Asserted by Dr. Henry's Counsel.

"In federal court, the determination of what is privileged depends upon the dictates of Rule 501 of the Federal Rules of Evidence." ERA Franchise Sys., Inc. v. N. Ins. Co. of N.Y., 183 F.R.D. 276, 278 (D. Kan. 1998). Rule 501 states that "in a civil case, state law

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governs privilege regarding a claim or defense for which state law supplies the rule of decision." Fed. R. Evid. 501. Under Rule 1101(c) of the Federal Rules of Evidence, "rules on privilege," such as Rule 501, "apply to all stages of a case or proceeding." As a result, Rule 501 is applicable in discovery proceedings – including depositions. Armour Int'l Co. v. Worldwide Cosmetics, Inc., 689 F.2d 134, 135 (7th Cir. 1982) (holding that Rule 501 "applies as well to discovery proceedings"); see also 8 Wright & Miller § 2016, at 221 (noting that the usual view is that "the same rules of privilege apply to discovery as apply at the trial"). Because Dr. Henry's counsel asserted a privilege in a federal case proceeding under the federal rules, Rule 501 provides the framework for determining whether testimony and opinions sought from Dr. Henry in his deposition are privileged. See Mem'l Hosp. for McHenry Cty. v. Shadur, 664 F.2d 1058, 1061 (7th Cir. 1981).

II. Wisconsin Law Supplies the Rule of Decision Regarding the **Application of State Privilege Law Under Rule 501.**

Determining which state's privilege law applies in the context of a nonparty deposition has been characterized as "among the most difficult questions a Federal judge can be called upon to answer." Mitsui & Co. (U.S.A.) Inc. v. Puerto Rico Water Res. Auth., 79 F.R.D. 72, 76 (D.P.R. 1978) (citing "The Federal Rules of Evidence: Rule 501 Klaxon and the Constitution," 5 Hofstra L. Rev. 21, 24 (1976); Note, . . . Cases "Privilege" in Federal Diversity Cases, 10 Nat. Res. J. 861 (1970)). Under Fed. R. Evid. 501, in diversity actions, questions of privilege are controlled by state law. See Fed. R. Evid. 501; In re California Pub. Utilities Comm'n, 892 F.2d 778, 781 (9th Cir. 1989) (citing Liew v. Breen, 640 F.2d 1046, 1049 (9th Cir.1981)). "Rule 501, however, does not tell us which state law the forum state should apply." KL Grp. v. Case, Kay & Lynch, 829 F.2d 909, 918 (9th Cir. 1987). The issue is complicated in the MDL context, where cases originate in many different states. In re: Bard IVC Filters Prod. Liab. Litig., No. MDL 15-2641 PHX DGC, 2016 WL 3970338, at *1 (D. Ariz. July 25, 2016). To resolve this issue, it is necessary to determine the "originating jurisdiction" and then apply that state's choice of law analysis.

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a. Wisconsin is the "originating jurisdiction."

In diversity cases transferred under the Judicial Panel on Multidistrict Litigation ("MDL"), the transferor court is considered the "forum" court for purposes of deciding the choice of law rules to apply to the case. In re: Bard IVC Filters Prod. Liab. Litig., No. MDL 15-2641 PHX DGC, 2016 WL 3970338, at *2 (D. Ariz. July 25, 2016); see also In re Korean Air Lines Co., Ltd., 642 F.3d 685, 699 (9th Cir. 2011) ("the MDL transferee" court is generally bound by the same substantive legal standards, if not always the same interpretation of them, as would have applied in the transferor court"); In re Nucorp Energy Sec. Litig., 772 F.2d 1486, 1492 (9th Cir. 1985) ("we must apply the choice of law rules of Illinois because the claims were originally filed in district court in Illinois before they were transferred to California by the Judicial Panel on Multidistrict Litigation"). For cases that originate outside the MDL court's judicial district and are filed directly into the MDL, many courts apply the choice-of-law rules of the "originating jurisdiction." Sanchez v. Boston Sci. Corp., No. 2:12-CV-05762, 2014 WL 202787, at *4 (S.D.W. Va. Jan. 17, 2014). In a prescription medical device MDL, the originating jurisdiction is the place where the device was implanted. See id. (holding that the "originating jurisdiction" is the state in which the plaintiff was implanted with the product and applying that state's choice of law rules).

Here, Dr. Henry's deposition was taken in connection with the *Hyde* bellwether case (Case No. 2:16-cv-00893-DGC). In *Hyde*, the filter was implanted in the state of Wisconsin. Further, in their Amended Master Short Form Complaint, the *Hyde* Plaintiffs have indicated that the Eastern District of Wisconsin should be considered the proper MDL transferor court absent direct filing. (*See* Case No. 2:16-cv-00893-DGC, Doc. No. 1.) Consequently, Wisconsin is the "originating jurisdiction" in the *Hyde* case and this Court must look to the law of Wisconsin in making a choice of law determination. *See Sanchez*, 2014 WL 202787, at *4.

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Under Wisconsin choice of law principles, Wisconsin law applies to Dr. Henry's assertion of privilege during his deposition.

In Wisconsin, the first rule in choice of law questions is that the law of the forum should presumptively apply unless it becomes clear that non-forum contacts are of the greater significance. *Stupak*, 287 F. Supp. 2d at 970–71 (citing *Gillette*, 251 Wis. 2d at 588, 641 N.W.2d at 672). Wisconsin courts also consider five factors in deciding which state's law to apply, although it is not entirely clear how they are to influence the determination once the "first rule" is applied. *Id.*, (citing *Hunker v. Royal Indem. Co.*, 57 Wis. 2d 588, 597, 204 N.W.2d 897, 901–902 (1973)). Those five factors include:

- (1) Predictability of results; (2) Maintenance of interstate and international order; (3) Simplification of the judicial task;
- (4) Advancement of the forum's governmental interests; and
- (5) Application of the better rule of law.

Id. (citing *Gillette*, 251 Wis. 2d at 588–589, 641 N.W.2d at 676).

Because Wisconsin is the "forum" state, Wisconsin law should presumptively apply under the "first" rule. Additionally, courts have held that, pursuant to Rules 26 and 37 of the Federal Rules of Civil Procedure, the forum court for determining privilege issues raised during the course of a deposition is the state where the deposition took place. *See Ex parte Sparrow*, 14 F.R.D. 351, 353 (N.D. Ala. 1953) (holding that court located where deposition took place is the forum court "[f]or the purpose of determining the witness' claim of privilege" because it is the place where, under Rules 26 and 37, "the proponent . . . is required to pursue his remedy to compel the witness to answer"); *see also Palmer v. Fisher*, 228 F.2d 603, 608–09 (7th Cir. 1955) *abrogated on other grounds by Carter Prod., Inc. v. Eversharp, Inc.*, 360 F.2d 868 (7th Cir. 1966) (holding that the forum law to be applied in determining privileges asserted at a deposition is the forum law of the state where the deposition was taken); Fed. R. Civ. P. 26(c) ("any person from whom discovery is sought may move for a protective order . . . on matters relating to a deposition, in the court for the district where the deposition will be taken"); Fed. R. Civ.

P. 37(a) ("A motion [to compel discovery] for an order to a nonparty must be made in the court where the discovery is or will be taken.")¹. Because Dr. Henry's deposition was taken in Wisconsin, Wisconsin is the forum state for determining his claims of privilege during his deposition and the law of Wisconsin should presumptively apply.

The result remains the same when the five factors enumerated in Gillette are applied. First, the application of Wisconsin law ensures predictability of results by enforcing the law of the deposition's location. Under such a rule, counsel and witnesses can easily and reliably determine the appropriate law governing privilege during the deposition merely by looking to the state in which the deposition is to take place. Second, applying Wisconsin law – as the location of the deposition – maintains interstate and international order by applying the state's law expected by the witness as opposed to that of an unforeseen jurisdiction. Third, following the location of deposition rule also greatly simplifies the judicial task of making choice of law determinations as it obviates the need for lengthy analysis of choice of law issues. Fourth, application of Wisconsin law also advances Wisconsin's governmental interests – as both the deposition forum and case forum – in enforcing its laws on privilege. Finally, application of Wisconsin law is simply the better legal rule because it offers a simple, fair, predictable approach to deciding matters of privilege raised in discovery proceedings that relate to individuals in that forum.

As a result, for purposes of Fed. R. Evid. 501, Wisconsin law should apply to Dr. Henry's privilege assertions during his deposition.

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¹ Under Fed. R. Civ. P. 45(f), subpoena-related motions may be transferred from the court where compliance is required to the issuing court if the person subject to the subpoena consents or if the court finds exceptional circumstances. If the motion is transferred, however, this Court, as the transferee court, should apply the same law which the transferor court would have applied. See Van Dusen v. Barrack, 376 U.S. 612, 639, 84 S. Ct. 805, 821, 11 L. Ed. 2d 945 (1964) ("We conclude, therefore, that in cases such as the present, where the defendants seek transfer, the transferee district court must be obligated to apply the state law that would have been applied if there had been no change of venue.").

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III. Wisconsin Law Supports the Objections and Instructions Made by Dr. Henry's Attorney.

a. Wisconsin recognizes a qualified privilege for expert witnesses which Dr. Henry is entitled to exercise.

Wisconsin recognizes a broad qualified privilege for expert witnesses. *Imposition of Sanctions in Alt v. Cline*, 224 Wis. 2d 72, 89, 589 N.W.2d 21, 27 (1999). The Supreme Court of Wisconsin has iterated the extent of the privilege as follows:

"[W]e hold that absent a showing of compelling circumstances, an expert cannot be compelled to give expert testimony whether the inquiry asks for the expert's existing opinions or would require further work. In addition to demonstrating a compelling need for the expert's testimony, the party seeking the expert's testimony must present a plan of reasonable compensation. Finally, if the party seeking an expert's opinion is able to show a compelling need for the expert's opinion, an expert can only be compelled to give existing opinions. Under no circumstances can an expert be required to do additional preparation."

Alt, 224 Wis. 2d at 89, 589 N.W.2d at 27. As the court explained, compelling circumstances may exist where "a particular expert's testimony is uniquely necessary" or "irreplaceable." *Id.*, 224 Wis. 2d at 88-89, 589 N.W.2d at 27. Such compelling circumstances do not exist, however, when there are "a number of people within a field with similar specialized knowledge capable of rendering an expert opinion on the question or questions asked." *Id.*

The facts presented in the *Alt* decision are instructive. The case involved a medical malpractice claim arising from a cesarean section birth. One of the physicians who provided the mother with prenatal care was deposed. At the deposition, the physician refused to answer the question, "No matter what the cause, a patient with a history of term

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pregnancy and a gush of blood[,] that's abnormal?" Id., 224 Wis. 2d at 79, 589 N.W.2d at 23. The court found that the question impermissibly sought privileged expert opinion and upheld the physician's right to refuse to answer. The court recognized that, in terms of fact testimony, the physician was "unique with respect to the prenatal care provided to [the mother] and he must testify as to his observations in that role." Id., 224 Wis. 2d at 90, 589 N.W.2d at 27. As to the physician's expert opinions, however, the court held that the physician's testimony was not unique because he was "no more and no less qualified than any other obstetrician to give an expert opinion about whether a gush of blood in a patient who has a history of term pregnancy is abnormal." *Id.*

In a later case, the Supreme Court of Wisconsin held that "the compelling circumstances determination must focus on whether there is unique or irreplaceable opinion testimony sought from an expert, not on procedural aspects of the case." Glenn v. *Plante*, 2004 WI 24, ¶ 29, 269 Wis. 2d 575, 594, 676 N.W.2d 413, 422. In *Glenn*, the Wisconsin court held that plaintiff's treating physician could not be compelled to provide expert testimony against his will even if the physician was, through the procedural posture of the case, plaintiff's only available expert for trial. The court recognized that "if [plaintiff's treating physician] does not testify and circuit court declines to permit the naming of additional expert witnesses, the [plaintiffs'] case may ultimately be dismissed." *Id.*, 269 Wis. 2d at 593–94, 676 N.W.2d at 422. The court, however, refused to give any substantial weight to that consideration noting that "barring counsel's failure to meet the appropriate deadline, the [plaintiffs] would have been able to draw upon the opinion testimony of another expert." *Id*.

Here.

. He has not

been retained by either side as an expert.

he cannot be forced to offer

expert testimony absent a showing of compelling circumstances. In that regard, Dr. Henry is no more and no less qualified than any other vascular and/or interventional radiologist

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to give an opinion in this case. As a result, he is entitled to invoke Wisconsin's broad qualified privilege for expert witnesses.

> Dr. Henry's attorney properly objected and instructed his client regarding application of the expert witness privilege to questions seeking Dr. Henry's expert opinion.

A question asks for expert testimony if it requires "scientific, technical, or other specialized knowledge" to answer the question. Alt, 224 Wis. 2d at 83, 589 N.W.2d at 25 (quoting Wis. Stat. § 907.02 (1993–94)). Such specialized knowledge is that which is not within the range of ordinary training or intelligence. *Id.* Asking for expert testimony calls upon persons of exceptional experience and qualifications to give their opinion. *Id.*

As shown by the deposition excerpts previously submitted to the Court on this issue, Dr. Henry's counsel objected and instructed Dr. Henry not to respond to six (6) questions posed by Plaintiffs' counsel. These questions were all iterations of the same basic hypothetical question asking Dr. Henry whether, if Bard knew that its filters carried a significant risk of injury or death, if that would be the type of information he would have wanted to know about in his clinical practice. See Depo. of David Henry, M.D., 28:11-16, 29:5-10, 31:15-20, 43:11-19, 46:1-16, 54:20-55:1. These questions are, by definition, hypothetical because they all require Dr. Henry to assume facts regarding Bard's alleged undisclosed knowledge concerning risks posed by their filters. Such questions necessarily ask for expert testimony because they require Dr. Henry to call upon his expertise as a doctor and then form an opinion on whether having the posited hypothetical knowledge would be desirable in treating his patients. The cited questions were generalized to Dr. Henry's entire medical practice and were not specific or limited to Ms. Hyde's treatment. Consequently, the questions required Dr. Henry to assume alleged hypothetical circumstances unknown to Dr. Henry at the time of his treatment and observation of Ms. Hyde and provide general opinions not directly applicable to her treatment. Dr. Henry would not be able to answer such questions without expressing an expert

opinion. As a result, Dr. Henry's counsel properly objected and instructed his client in asserting the *Alt* privilege in response to these questions.

Plaintiffs' counsel also attempted to have Dr. Henry review a number of documents which Dr. Henry did not previously review as part of his treatment of Ms. Hyde. *See* Depo. of David Henry, M.D., 60:15-23. Dr. Henry's counsel objected and instructed his client not to review the materials or answer any questions concerning them. *Id.*, at 60:24-61:15. Under Wisconsin law, "[u]nder no circumstances can an expert be required to do additional preparation." *Alt*, 224 Wis. 2d at 89, 589 N.W.2d at 27. "Additional preparation" has been described as "further study, experimentation, thought or reflection" or "any out-of-court preparation[.]" *Id.*, 224 Wis. 2d at 87, 589 N.W.2d at 26. Reviewing the additional materials as requested by Plaintiffs' counsel would have required further study, thought, or reflection and, thus, would have constituted "additional preparation." Consequently, the objections and instructions by Dr. Henry's counsel were appropriate.

IV. <u>Dr. Henry's Privilege-Based Objections Did Not Obstruct Plaintiffs'</u> <u>Counsel from Seeking Required Testimony Under the Learned Intermediary Doctrine Relevant to the Issue of Causation for Failure-to-Warn Claims.</u>

Though the Wisconsin Supreme Court has not yet addressed the application of the learned intermediary doctrine, federal courts applying Wisconsin law have predicted that Wisconsin would apply that doctrine to prescription medical device cases. *See In re Zimmer Nexgen Knee Implant Prod. Liab. Litig.*, 218 F. Supp. 3d 700, 727–28 (N.D. Ill. 2016) ("given the widespread acceptance of the doctrine throughout the country, the court believes it is likely that the Wisconsin Supreme Court would apply the learned intermediary doctrine in this case."); *Menges v. Depuy Motech, Inc.*, 61 F. Supp. 2d 817, 830 (N.D. Ind. 1999); *Monson v. AcroMed Corp.*, No. 96-C-1336, 1999 WL 1133273, at *20 (E.D. Wis. May 12, 1999); *Lukasiewicz v. Ortho Pharmaceutical Corp.*, 510 F. Supp. 961, 963 (E.D. Wis. 1981), *modified on other grounds*, 523 F. Supp. 206 (E.D. Wis. 1981).

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Bard anticipates that Plaintiffs will argue that Dr. Henry's assertion of his Alt privilege interfered with Plaintiffs' counsel's ability to ask questions relevant to Wisconsin's predicted application of that doctrine.

Under the learned intermediary doctrine, in order to prove causation on their failure-to-warn claims, Plaintiffs must present evidence that Dr. Henry, as the implanting physician, would not have implanted the filter in Ms. Hyde had a different warning been provided to him. *In re Zimmer*, 218 F. Supp. 3d at 728 (holding that in medical device cases, under Wisconsin law, plaintiffs must present evidence that the implanting physician would have altered his or her behavior in light of a change to the device's instructions for use). Plaintiffs may argue that Dr. Henry's privileged-based objections inhibited them from obtaining testimony on that issue and that application of the learned intermediary doctrine presents a compelling circumstance supporting the Court's abrogation of Dr. Henry's Alt privilege and requiring him to submit to a second deposition to provide testimony relevant to the doctrine. However, Dr. Henry has already provided the testimony sought by Plaintiffs free of Alt or other objection.

The Alt objections made by Dr. Henry's counsel to Plaintiffs' questions regarding alternative warnings were narrowly limited to questions which sought generalized expert opinions not tethered to Ms. Hyde's treatment and, with invitation by Dr. Henry's counsel to rephrase each question to tie it specifically to Ms. Hyde's treatment. When Plaintiffs' counsel rephrased the questions to tie them directly to Dr. Henry's treatment of Ms. Hyde - i.e., the type of questions required in order to prove causation on their failure-to-warn claims under the learned intermediary doctrine – Dr. Henry answered the questions without objection. See Depo. of David Henry, M.D., 43:5-45:12, 46:1-25, 54:20-56:18.

As shown by the examples cited above, when their questions were limited specifically to Ms. Hyde's treatment, Plaintiffs were unobstructed in seeking testimony from Dr. Henry relevant to the issue of causation for their failure-to-warn claims. Under the Wisconsin court's decision in *Alt*, Dr. Henry is compelled to answer questions related to the treatment of Ms. Hyde. See Alt, 224 Wis. 2d at 90, 589 N.W.2d at 27 (holding that

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treating physician must offer unique, factual testimony regarding patient's treatment).
Dr. Henry's Alt privilege is, therefore, completely compatible with the application of the
learned intermediary doctrine to this case. Plaintiffs' counsel had the opportunity to – and
did - ask Dr. Henry questions required to prove causation on Plaintiffs' failure to warn
claims under that doctrine without objection. Dr. Henry's deposition should not be re-
taken simply so that Plaintiffs' counsel may solicit more favorable answers.

CONCLUSION

For all of the foregoing reasons, this Court should deny Plaintiffs' counsel's request to retake Dr. Henry's deposition.

This 28th day of July, 2017.

/s/ Matthew B. Lerner

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Attorney for Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on July 28, 2017, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send notification of such filing to all counsel of record.

/s/ Matthew B. Lerner Matthew B. Lerner Georgia Bar No. 446986

7028-Plaintiffs' Memorandum of Issues Regarding the Deposition of David Henry, M.D. Filed Redacted

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9	UNITED STATE	S DISTRICT COURT	
10	DISTRICT	OF ARIZONA	
11	In Re Bard IVC Filters Products	No. MD-15-02641-PHX-DGC	
12	Liability Litigation	PLAINTIFFS' MEMORANDUM OF	
13		ISSUES REGARDING THE DEPOSITION OF DAVID HENRY, M.D.	
14		, in the second	
15	LISA HYDE and MARK HYDE, a married couple,		
16	Plaintiffs,		
17	V.		
18	C.R. BARD, INC., a New Jersey		
19	corporation and BARD PERIPHERAL VASCULAR, an Arizona corporation,		
20	Defendants.		
21			
22	MEMORANDUM OF PO	DINTS AND AUTHORITIES	
23	I. INTRODUCTION		
24	On April 6, 2017, the deposition of J	David Henry, M.D. ("Dr. Henry") was taken in	
25	this action.		
26			
27	During Dr. Henry's deposition, his counsel	made objections on the basis of privilege and	
28	instructed Dr. Henry not to provide answer		
-0		Tot the same	

reason, Dr. Henry's lawyer refused to allow Dr. Henry to look at internal Bard documents obtained through discovery and disallowed questioning as to same.

On July 14, 2017, this Court entered Case Management Order No. 26 in which the parties were ordered to file memoranda addressing the following issues: (1) Does Federal Rule of Evidence ("FRE") 501 apply to the privilege asserted by Dr. Henry's counsel? (2) If so, what state law supplies the rule of decision within the meaning of Rule 501? (3) Does the applicable state law support the objection and instruction made by Dr. Henry's attorney? (4) Even if the instruction and objection were appropriate in the normal case, does assertion of the learned intermediary defense mean that the objection and instruction should not be permitted?

Preliminarily, Plaintiffs' position is that FRE 501applies and that the applicable state law of Wisconsin does not support the objection and instruction made by Dr. Henry's attorney. Additionally, Dr. Henry's voluntary offering of expert testimony in response to other questions constitutes a waiver of any privilege his counsel asserted. Finally, if the Learned Intermediary Doctrine is asserted, the objections and instructions given during Dr. Henry's deposition should not be permitted.

II. ARGUMENT AND RESPONSES TO THE COURT'S QUESTIONS

A. FRE 501 Applies to the Privilege Asserted by Dr. Henry's Counsel

Rule 501provides the federal rule of evidence regarding privilege, in general. It states, in pertinent part, that "in a civil case, state law governs privilege regarding a claim or defense for which state law supplies the rule of decision." Fed. R. Evid. 501.

Since there is no other codified federal rule of evidence regarding the issue of privilege, FRE 501 applies. As it is written, FRE 501 makes clear that in civil cases, such as this, state law is the governing authority regarding counsel's objection on the basis of privilege in Dr. Henry's deposition.

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B. Wisconsin Law Supplies the Rule of Decision Within the Meaning of FRE 501.

FRE 501 is silent about which state's privilege law to apply when state law controls and the litigation has contacts with two or more states. *Wolpin v. Philip Morris, Inc.*, 189 F.R.D. 418, 423 (C.D. Cal. 1999) ("the rule does not specify which state law should be applied"). The Ninth Circuit has held that courts should apply the privilege law of the state that would be chosen under the choice-of-law rules used by the state where the court sits. *Wolpin*, 189 F.R.D. at 423.

When it comes to the specific issue of an asserted privilege at a deposition or other discovery preceding that occurs in a forum other than the one in which the case is pending, however, the forum in which the deposition occurred will supply the choice-of-law rule. *Id. Weinstein's Federal Evidence* § 501.02[3][c][ii] states that courts usually apply the law of the state where the deposition is being taken where the state of the deposition and the state of the underlying action differ. Therefore, Wisconsin's choice-of-law rule should decide which state's law governs the privilege issue.

The Wisconsin Supreme Court has stated that when determining choice-of-law issues, "Wisconsin courts apply the 'grouping of contacts' rule, that is, rights must be determined by the law of the jurisdiction with which the contact has its most significant relationship." *State Farm Mut. Auto Ins. Co. v. Gillette*, 251 Wis. 2d 561 (2002).

Here, Wisconsin is the place with the most significant relationship to Dr. Henry's privilege assertion. It is where the deposition took place, it is where Dr. Henry is located, it is where Dr. Henry treated Mrs. Hyde, and it is where the privilege itself was asserted. As such, Wisconsin law supplies the rule of decision with specific regard to the privilege and objection asserted by Dr. Henry.

- C. <u>Wisconsin Law Does Not Support the Asserted Objections and Instructions.</u>
 - 1. Dr. Henry's testimony is not privileged under Wisconsin law.

Throughout the deposition, Dr. Henry's counsel objected to certain questions, asserting a privilege against providing expert opinions and instructed Dr. Henry not to

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provide an answer. Under Wisconsin law pertaining to the doctrine of privilege, however, Dr. Henry should have been able to provide responses, as the questions asked were not within the ambit of Wisconsin's privilege law.

The pertinent Wisconsin law regarding a physician's obligation to provide "expert" testimony stems from Burnett v. Alt, 589 N.W.2d 21 (Wis. 1999). In that case, the court ultimately recognized a physician's privilege not to provide professional opinions except in certain circumstances. As basis for that conclusion, the court found that "the opinion of one expert is not irreplaceable. '[U]nlike factual testimony, expert testimony is not unique and a litigant will not usually be deprived of critical evidence if he cannot have the expert of his choice." Id. at 27 (quoting Mason v. Robinson, 340 N.W.2d 236, 242 (Iowa 1983)). The *Alt* court determined that a question asks for expert testimony if it requires "scientific, technical, or other specialized knowledge to answer the question." *Id.* at 25. The court held that, where a question seeks expert testimony, the examining party must meet the following criteria necessary to elicit a professional opinion from a physician: (1) a compelling circumstance; (2) the party seeking the testimony has to have presented a plan for reasonable compensation of the expert; and (3) the expert will not be required to do additional preparation for the testimony. See id. at 27. The court concluded that "while [the physician] had to testify regarding his observations made during the prenatal care he provided to [plaintiff], [the physician] was not so unique as to be required to answer a deposition question that required his expert opinion about another physician's treatment." See Glenn v. Plante, 676 N.W.2d 413, 421 (Wis. 2004) (emphasis added).

The Wisconsin Supreme Court clarified its *Alt* holding in *Glenn v. Plante*, 676 N.W.2d 413, stating that the *Alt* privilege "does not apply to observations made by a person's treating physician regarding the care and treatment provided to the patient, but rather applies to expert testimony from such a physician as to the standard of care and treatment provided by *another* physician." *Id.* at 415. There, again, a treating physician of the plaintiff was asked to provide expert opinion testimony regarding the standard of care applicable to another physician. *Id.* at 422. However, the court "conclude[d] that a

treating physician may still be required to testify regarding his or her observations relating to the care or treatment provided to his or her patient, as such compulsion is considerably different than forcing a physician to testify as to the standard of care and treatment provided by another physician." *Id.*; *see also id.* at 423 ("we emphasize that a physician can be required to testify as to his or her own observations regarding his or her care and treatment provided to the patient while serving as the patient's treating physician"). And, a year later, in *Carney-Hayes v. Northwest Wisconsin Home Care, Inc.*, 699 N.W.2d 524 (Wis. 2005), "reaffirm[ing] [its] holdings in *Alt* and *Glenn* and [] clarify[ing] the duties and privileges of medical witnesses in a medical malpractice case," the Wisconsin Supreme Court stated: "A medical witness must testify about her own conduct relevant to the case, including her observations and her thought processes, her treatment of the patient, why she took or did not take certain actions, what institutional rules she believed applied to her conduct, and her training and education pertaining to the relevant subject." *Id.* at 529.

In other words, the privilege in *Alt* does not apply when a doctor is asked about his own decisions and actions, but rather applies when asked to testify about how a reasonable doctor would have handled a certain medical situation. Here, Dr. Henry was asked questions about his own decision-making process in treating Plaintiff Lisa Hyde. The questions presented at Dr. Henry's deposition did not necessitate him rendering an opinion about what a different doctor might do; rather, he was asked about what he did and what information was or would have been important to him in making decisions about Ms. Hyde's care. Consequently, he should have provided answers as a treating physician in this case.

Dr. Henry's counsel inappropriately objected a number of times to questions concerning Dr. Henry's own state of mind in his care and treatment of Plaintiff Lisa Hyde. The following is illustrative of such a question to which counsel incorrectly asserted a privilege:

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Q.	D vou	ır	, 11
	an IVC filter carried with it death, that would be importa	a significant potenti int information to you	al for serious injury of
Depositio	n Transcript of David Henry,	M.D., April 6, 2017	("Henry Dep. Tr."), at
28:11-16	(emphasis added). The ques	stion asked by Plainti	ffs' counsel was not
objectiona	able under Wisconsin law as i	it did not require	
		Even after Plaintif	fs' counsel re-phrased

the question, Dr. Henry's counsel again asserted a privilege and instructed Dr. Henry not to answer the following:

O. . and the company knew about that, wanted them to tell **you** that, fair to say?

Henry Dep. Tr. at 29:5-10 (emphasis added).

Dr. Henry's counsel's objection and instruction not to answer here was inappropriate and a misapplication of Wisconsin's privilege under Alt, Glenn, and Carney-Hayes. Under Wisconsin law, Dr. Henry was required to answer any question regarding his "own conduct relevant to the case," which includes his observations and treatment of Mrs. Hyde, why he did or did not take certain actions and "what institutional rules and regulations [he] believed applied to [his] conduct." Carney-Hayes, 699 N.W.2d at 529. This particular question was confined to Dr. Henry's own state of mind during his care and treatment of Plaintiff Lisa Hyde; he was simply asked what information he would have considered relevant to his clinical judgment at the time. Nothing about the question called for Dr. Henry to draw upon his expertise to respond to something beyond his own factual involvement in this case.

Dr. Henry's attorney instructed him not to answer similar questioning on the basis of privilege throughout the deposition. Those instructions, however, were misguided, as

¹ The parties stipulated to the filing under seal of the transcript of Dr. Henry's deposition. Defendants have filed the transcript as Sealed Lodged document at Doc. No. 7012.

each of the questions pertained to his understanding and state of mind during his treatment of Mrs. Hyde. For example, after being asked if anyone from Bard had told him prior to that the Recover filter migrated three times the industry average, Dr. Henry was instructed not to answer the following follow-up question:

Q. Is that the type of information **you** would have found useful in **your** clinical practice to determine which filter to use?

Henry Dep. Tr. at 43:11-13 (emphasis added). Again, the question was narrowed to the relevant time period and to what Dr. Henry would find useful in his own clinical practice in determining which filter to use in his care and treatment of Mrs. Hyde and his counsel's instruction was inappropriately asserted.

Finally, Dr. Henry's attorney stated he would assert the privilege and not permit Dr. Henry to testify in response to any questions regarding documents he had not seen. *Id.* at 60:15-61:24. Plaintiffs' counsel intended to ask Dr. Henry if he was aware of certain relevant facts contained in internal Bard documents at the time of his decision to implant the IVC filter in Mrs. Hyde and whether such facts could or would have impacted his decision to prescribe and implant that filter. As with Plaintiffs' other questions, these questions and the subject matter do not fall within the *Alt* privilege: they relate specifically to the witness doctor's "own conduct", "observations", and "thought processes." *Carney-Hayes*, 699 N.W.2d at 529. What the physician knew or did not know at the time of making a medical decision is not expert testimony; and how such knowledge would have impacted his or her particular actions – actions at issue in this litigation – is likewise not expert testimony. It is core fact testimony; and, in light of Bard's assertion of the learned intermediary doctrine, it is important fact information. There is simply no basis under Wisconsin law that supports the assertion of a privilege to those questions; to the contrary, Dr. Henry "must" testify regarding his care and treatment of his patient.

2. <u>Dr. Henry waived any privilege by voluntarily providing expert opinion testimony.</u>

As is the case in most states, privilege can be waived in Wisconsin by voluntary disclosure. A person waives a privilege if that person "voluntarily discloses or consents to disclosure of any significant part of the matter or communication." Wis. Stat. § 905.11.

In this case, Dr. Henry waived his right not to offer expert testimony by voluntarily offering opinions outside of his own care and treatment of Lisa Hyde. He voluntarily offered testimony concerning what decisions other medical doctors make and why; this is the type of testimony that *Alt* was meant to protect and by divulging an opinion drawn upon his expertise, Dr. Henry waived the privilege altogether. The following is an example of such testimony:

- **Q.** What I'm trying to learn is I take it **some** patients cannot be put on blood thinners; is that correct?
- **A.** Yeah. **Some patients** it would be considered risky. **They** might have predisposing conditions that would warrant maybe some caution in using blood thinners. Those are the types of decisions that **a lot of internal medicine doctors** might make.

Henry Dep. Tr. at 69:9-17 (emphasis added). Clearly, the doctor was drawing upon his own expertise and specialized training to provide testimony regarding what other doctors do and consider with some patients rather than providing factual testimony concerning his own care and treatment of Plaintiff Lisa Hyde. This voluntary disclosure of his expert opinion during the deposition constitutes a waiver of the privilege.

In *Alt*, the court determined that a question regarding what was "normal" or "abnormal" solicited an expert opinion. *Burnett v. Alt* at 84. The court reasoned that what was considered "normal" or "abnormal" could only be answered "in any meaningful and relevant way by a trained physician." *Id.* It would follow from this line of reasoning, that determining what is "reasonable" or "unreasonable" in the medical community is also a question that could only be answered by a trained physician and that it would be the very sort of testimony protected by the *Alt* privilege. Dr. Henry's voluntary testimony

regarding reasonableness also served as a waiver of his privilege not to provide expert testimony:

A. I would say that the patient's health care is a dynamic thing, and **a patient** that's had a couple of episodes of clots and pulmonary emboli, that the decision about whether it should stay or be retrieved, it's hard to speculate whether and under what circumstances that the filter may no longer be necessary.

And it's hard to prejudge the situation, and so I can't speculate. But now that I understand the record – and I don't know what's happened with this patient, but I think **it would be reasonable** to get a hematologist or somebody else stating that it's no longer needed rather than me try to speculate on whether it was or wasn't.

Henry Dep. Tr. at 89:18-24 (emphasis added). Despite being asked specifically about his care and treatment of Lisa Hyde in 2011 at this point of the deposition, the doctor provided a lengthy response about a hypothetical patient, in general, and what would be *reasonable* in the medical community regarding the decision whether to retrieve an IVC filter. Dr. Henry did not offer any statement, in fact, pertaining to his own observations or treatment of the plaintiff. The voluntary testimony provided by Dr. Henry regarding reasonable practice among physicians in their care and treatment of other patients is another example of Dr. Henry's waiver of the *Alt* privilege.

Voluntarily providing expert testimony in a deposition to certain questions despite asserting a privilege to avoid answering other questions cannot be reconciled and should not be permitted. The principle of waiver should be applied in this instance.

D. <u>The Objections and Instructions Unfairly Prejudice Plaintiffs from Disputing a Learned Intermediary Defense; There is a Compelling Reason to Require Testimony from Dr. Henry on These Issues.</u>

For failure to warn claims generally, a plaintiff must demonstrate that the warnings associated with a product that allegedly caused harm to that plaintiff was inadequate. In defense to such claim, medical device manufacturers can assert the learned intermediary defense, by which the manufacturer attempts to shift the focus for responsibility to warn users of the risks associated with its device from the manufacture to the prescribing physician. Under the doctrine, if the manufacture provides appropriate warnings to the prescribing physicians, the manufacture may have met its duty. Or, if the prescribing

physician was aware of the risks associated with a device, the failure to warn the patient of those risks may be an intervening cause of the patient's injuries. Thus, in part, the warnings given to the physician and the physician's knowledge or the risks are important to this affirmative defense. Similarly, a plaintiff should be able to demonstrate that a proper warning would have changed the decision of the treating physician. In other words, but for the inadequate warning, the treating physician would not have used or prescribed the product.

That Bard has asserted the learned intermediary defense in this case further highlights the inappropriateness of Dr. Henry's counsel's objections and instructions to his client not to answer certain questions at the deposition, and the need for Plaintiffs to

highlights the inappropriateness of Dr. Henry's counsel's objections and instructions to his client not to answer certain questions at the deposition, and the need for Plaintiffs to have a second deposition of Dr. Henry. Without a full and fair examination of Dr. Henry on the true level of his learnedness, Bard can assert the defense – contending that Dr. Henry was fully and

Mrs. Hyde having the ability to challenge that claim.

Even for expert testimony privileged under *Alt*, a physician may be compelled to testify where the party seeking the testimony establishes: (1) a compelling circumstance; (2) the party seeking the testimony has to have presented a plan for reasonable compensation of the expert; and (3) the expert will not be required to do additional

1	preparation for the testimony. Alt, 589 N.W.2d at 27. Those elements are met here. If	
2	Dr. Henry's testimony regarding what he knew or did not know at	
3	is somehow privileged, there is certainly a compelling	
4	circumstance to require his testimony here. Without his testimony, Plaintiff Lisa Hyde is	
5	handicapped in her ability to address Bard's learned intermediary defense. Without Dr.	
6	Henry's testimony as to what he knew or did not know at the time, it is virtually	
7	impossible to prove whether he was "learned" or "not learned." The other elements of Alt	
8	are easily met: Dr. Henry was paid for his testimony at a rate set by him and he would be	
9	paid for his time at his next deposition; and there is no "additional" preparation necessary	
10	by Dr. Henry for his testimony. Whether he was aware or unaware of certain facts at the	
11	time of implantation is a question of fact and his memory; whether those facts would have	
12	impacted his decisions, likewise, are case-specific to his own actions and require only his	
13	personal knowledge of what he did or would have done in providing the treatment he did	
14	to this particular patient.	
15	III. CONCLUSION	
16	The objections and instructions asserted during Dr. Henry's deposition were	
17	inappropriate and unsupported by applicable law. As such, Plaintiffs respectfully request	
18	permission to re-depose him.	
19	RESPECTFULLY SUBMITTED this 28th day of July 2017.	
20	GALLAGHER & KENNEDY, P.A.	
21		
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28	Co-Lead/Liaison Counsel for Plaintiffs	

CERTIFICATE OF SERVICE I hereby certify that on July 28, 2017, a true and correct copy of the foregoing was sent via U.S. Mail and/or Electronic Mail to: James R. Condo Amanda Sheridan Snell & Wilmer LLP 400 East Van Buren Street, Suite 1900 Phoenix, Arizona 85004 Attorneys for Defendants Richard B. North, Jr. Matthew Lerner Nelson Mullins Riley & Scarborough LLP 201 17th Street NW, Suite 1700 Atlanta, Georgia 30363 Attorneys for Defendants *Counsel for Plaintiffs will be served in accordance with the Court's Case Management Order No. 1 /s/ Deborah Yanazzo Deborah Yanazzo

David Henry, M.D. Deposition Transcript Dated April 6, 2017 - Filed Redacted

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            UNITED STATES DISTRICT COURT
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                DISTRICT OF ARIZONA
    In Re Bard IVC Filters Products
    Liability Litigation
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                         No. MD-15-02641-PHX-DGC
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        DO NOT DISCLOSE - SUBJECT TO FURTHER
                CONFIDENTIALITY REVIEW
11
     VIDEOTAPED DEPOSITION OF DAVID HENRY, M.D.
12
             TAKEN AT: Leib Knott Gaynor
       LOCATED AT: 219 North Milwaukee Street
13
                    Milwaukee, WI
14
                    April 6, 2017
15
               10:07 a.m. to 12:28 p.m.
16
              REPORTED BY ANITA K. FOSS
           REGISTERED PROFESSIONAL REPORTER
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14	
4.5	I N D E X
15	
16	Examination by Page
17	Mr. Saeltzer 4
18	Ms. Daly
19	EXHIBITS
20	
20	Page Exhibit No. Description Identified
21	Exhibit No. Description identified
21	2128 Journal article
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_ _	2129 Dr. Henry's records of patient 62
23	212) Dr. Henry B records or pactene 02
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- 1 TRANSCRIPT OF PROCEEDINGS
- THE VIDEOGRAPHER: Good morning. We are
- on the record. My name is Jon Hansen, CLVS, and
- 4 I'm the videographer for Golkow Technologies.
- 5 Today's date, April 6, 2017. The time is 10:07.
- 6 This video deposition is being held
- 7 in Milwaukee, Wisconsin, in the matter of Bard IVC
- 8 Filters Products Liability Litigation in the United
- 9 States District Court, District of Arizona, case
- number MD-1502641-PHX-DGC. The deponent today,
- 11 David Henry, M.D.
- 12 At this time if counsel could
- 13 please state their appearance for the record, after
- 14 which our reporter will swear in the witness and we
- can proceed.
- MR. SAELTZER: Douglas Saeltzer for the
- 17 plaintiff, Ms. Hyde.
- MS. DALY: Taylor Daly for the Bard
- defendants.
- MR. LEIB: And I'm Samuel Leib, appearing
- on behalf of Dr. Henry.
- DAVID HENRY, MD, called as a witness
- herein, having been first duly sworn on oath, was
- examined and testified as follows:
- EXAMINATION

- 1 BY MR. SAELTZER:
- Q. Good morning, Doctor. My name is Douglas
- 3 Saeltzer. I'm going to be conducting an
- 4 examination, which is asking you some questions for
- 5 a trial involving one of your patients, against
- 6 Bard. Do you understand that, Doctor?
- 7 A. I do.
- Q. Do you understand that neither your
- 9 patient, Ms. Hyde, nor Bard or anybody here, is
- making any allegation you did anything wrong? And
- do you understand that you're not the subject of
- 12 this lawsuit?
- 13 A. Yes.
- Q. This video may be played for the jury in
- the event this goes to trial, so I'll be asking you
- questions for the jury's benefit and phrasing them
- that way sometimes, even though we're in a
- 18 conference room, okay, Doctor?
- 19 A. Yes.
- Q. And Doctor, do you practice medicine
- generally in the greater Milwaukee, Wisconsin area?
- A. Currently, no.
- 23

- Q. Are we currently in Milwaukee today?
- A. We are, yes.
- 5 Q. For the jury's benefit, the date today,
- 6 we are in March of 2017?
- 7 A. Yes.
- Q. Actually, it would be April.
- 9 A. Yes, you're right.
- 10 Q. Doctor, have you ever had your deposition
- 11 taken before?
- 12 A. I have.
- Q. About how many times?
- 14 A. Three times.
- Q. So you're somewhat familiar with the
- 16 process; correct?
- 17 A. Somewhat.
- 18 Q. If I ask you a question you don't
- understand, Doctor, please tell me you don't
- understand the question. Will you do that for me,
- 21 Doctor?
- 22 A. Yes.
- Q. Likewise, if I interrupt you and you
- haven't completed your answer, please tell me I've
- interrupted you so I know to be quiet so we can

- 1 have the benefit of your full testimony. Okay,
- 2 Doctor?
- A. Yes.
- Q. Please try to speak up so that your
- 5 testimony will be captured and recorded accurately.
- 6 Sometimes we all start whispering. I may remind
- 7 you of that. Okay, Doctor?
- 8 A. Yes.
- 9 Q. Let me just start with your background
- 10 and training and introduce you to the jury. Can
- 11 you give me an overview of your education?
- 12 A. Sure. I attended Craig University School
- of Medicine, followed by a radiology residency in
- 14 Chicago at Michael Reese Hospital, followed by a
- 15 fellowship in interventional radiology at
- 16 Northwestern.
- Q. What year did you graduate medical
- 18 school?
- A. Forgive me, I want to make sure I'm
- 20 right, here. 1990.
- Q. Did you immediately transition into your
- radiology residency program in Chicago after
- 23 graduation from medical school?
- A. Let me make sure. For the record, I
- graduated from high school in '78. I graduated

- 1 college in '82. I graduated from medical school in
- ² '86. I did a four-year radiology residency from
- 3 '86 to '90, and from '90 to '91 I did a fellowship.
- 4 Q. Could you explain to the jury what a
- 5 residency program is?
- 6 A. It's a training period for -- for
- 7 physicians to get credentialed in an area of
- 8 medical subspecialty.
- 9 Q. So this is training that you receive
- 10 after you've graduated medical school and are a
- 11 doctor?
- 12 A. Correct.
- Q. You mentioned it was four years in
- 14 Chicago in radiology?
- 15 A. Correct.
- Q. Did you have any subspecialty within your
- 17 radiology residency?
- 18 A. No.
- Q. General overview of the training that you
- received in the residency is what?
- A. We interpret x-rays and we're -- we study
- 22 anatomy, interpretation of CAT scans, ultrasounds,
- MRIs, all medical imaging, diseases that can be
- seen on x-rays. And that about sums it up.
- Q. Did you have any training, during your

- 1 four-year residency program in Chicago, in
- ² interventional radiology?
- A. Not during those four years, no.
- Q. When I use the term "interventional
- 5 radiology," what does that mean to you?
- 6 A. It's an area of radiology that
- 7 encompasses using the x-ray equipment to do minor
- 8 procedures.
- 9 Q. Can you give me an example of some of the
- interventional procedures you're trained to
- 11 perform?
- 12 A. Well, we might do biopsies, we might put
- catheters in patients, we might do -- treat certain
- 14 diseases using the x-ray equipment with our
- knowledge of -- of the disease process and the
- anatomy.
- Q. Getting back to your training. And I
- 18 apologize, I'm getting over a bit of a head cold.
- 19 If you can't understand me, again, don't feel rude
- 20 about -- about letting me know.
- Can you tell us -- or you
- mentioned you went through a fellowship after
- residency. Did your fellowship immediately follow
- your residency?
- 25 A. It did.

- 1 Q. Do all radiologists go through a
- fellowship?
- 3 A. No.
- Q. What was your fellowship? Well, strike
- 5 the question. What is the fellowship?
- A. What is a fellowship?
- 7 Q. Sure. How does it tie into training?
- A. It's an extra year. People put it on the
- 9 end of their training to -- and it may offer them,
- or offer the market, the public health care market,
- 11 some area of extra training.
- Q. What did you do your fellowship at
- 13 Northwestern in?
- 14 A. Interventional radiology.
- Q. As part of your fellowship training, did
- you receive any training or exposure to the use of
- 17 IVC, or inferior vena cava filters?
- 18 A. I did.
- Q. Can you briefly describe for the jury
- what your experience was for -- if I use the term
- IVC filters, are you familiar with that term?
- 22 A. Yes.
- Q. Okay. What was your experience with IVC
- filters in your fellowship at Northwestern?
- A. We put them in when need be.

- Q. Can you give the jury some idea as to
- what percent of your fellowship or how frequently
- in your fellowship you would have been trained on
- 4 implanting IVC filters?
- 5 A. Maybe it was five to ten percent. Not
- 6 even ten. Maybe five percent total.
- 7 Q. Would this training be the type where you
- 8 have a more senior doctor supervising you in the
- operating room, demonstrating for you how to do the
- 10 procedure?
- 11 A. Yes.
- Q. And also then watching you perform the
- procedure and instructing you as you're actually
- doing the procedure?
- 15 A. Yes.
- Q. Following your fellowship in 1991, where
- did you go work?
- 18 A. I worked for a year in Chicago,
- 19 moonlighting. And then I met my wife, I took a job
- in Ohio, and I worked there for I think 13 or
- 21 14 years.
- Q. Working within the specialty of
- 23 interventional radiology?
- A. No, general radiology.
- Q. Did you have any exposure to

- interventional radiology procedures during that 13
- 2 to 14 years in Ohio?
- A. Yes.
- 4 Q. About what percentage or practice, while
- you were in Ohio for those 14 years, was
- 6 interventional radiology as opposed to general
- 7 radiology?
- A. Maybe 25 percent, 30 percent.
- 9 Q. Did that include implanting IVC filters?
- 10 A. Yes.

- Q. Have you had an opportunity to review any
- medical records to refresh your recollection about
- 16 that patient?
- 17 A. I was here yesterday and I had -- I
- 18 reviewed a one -- my -- I think my -- my report of
- 19 the procedure.
- Q. That procedure was what?
- 21 A.
- A. I believe it may have been, but I'm not
- 24 sure.
- Q. Was that procedure -- or did that

1 procedure occur on ; does that sound about right? 2 3 Α. I think that that's what was on the piece 4 of paper. 5 Okay. So just to verify for the jury, Q. you don't have any independent recollection of that 6 7 encounter; correct? 8 Α. Correct, yes. 9 And it was a brief encounter? Ο. 10 Α. Yes. 11 Ο. And it was one encounter? 12 Α. Yes. 13 Okay. So I have the date, Q. , as a milepost here as I'm going through your 15 training and experience, and I'll use that. You've 16 said you were working in Ohio for 13 to 14 years. Where did you go after Ohio? 17 18 To Milwaukee. Α. 19 About what year? My math isn't good. Q. 20 What year did you come to Milwaukee? I think it was between 2000 and 2001. 21 Α. 22

- Q. Did you practice within the subspecialty
- of interventional radiology during that time?
- A. I was mostly a general radiologist.
- 4 Q. Did you do some interventional
- 5 procedures?
- 6 A. I did.
- Q. Did your practice remain roughly
- 8 consistent throughout that time period, meaning
- 9 mostly general radiology with some interventional
- 10 radiology?
- 11 A. Yes.
- 12 Q. Are you board certified in any
- 13 specialties, Doctor?
- 14 A. I'm board certified in diagnostic
- radiology and interventional radiology.
- Q. When did you first become board certified
- in either of those specialties?
- 18 A. I became board certified in diagnostic
- 19 radiology one or two years after the completion of
- my residency.
- Q. Did you successfully complete those
- 22 boards your first try?
- A. I did not.
- Q. They're difficult boards?
- 25 A. They are.

- Q. And you then were board certified in
- 2 diagnostic radiology; correct?
- A. Correct.
- Q. And have remained so up to today?
- 5 A. It's lifetime, yes.
- 6 Q. And how about interventional radiology?
- 7 A. Interventional radiology, I became board
- 8 certified -- that's a good question. The
- 9 certification there is ten years, it's not
- 10 lifetime. And I've been board certified throughout
- 11 my career. I don't know when I first -- I don't
- 12 recall when I first -- I think it was within a year
- or two of my completion of my fellowship.
- Q. At any rate, were you board certified in
- interventional radiology at the time you



- 18 A. Yes.
- 19 Q. Do you consider yourself as having any
- subspecialty within the field of radiology?
- 21 A. Yeah, I do interventional radiology, but
- not a hundred percent.
- Q. Let's focus around the time period, say
- the six months, year, before the . I
- want to get an understanding for the jury of your

- 1 practice and how you spent your time. I don't want
- to be rigid in my time period. If you want to use
- a little different time period, feel free to do
- 4 that, okay? But the purpose of these questions is
- 5 to give the jury an understanding as to what you
- 6 did on a day-to-day basis back in, you know, the
- 7 time period leading up to
- You understand that, Doctor?
- 9 A. Sure.
- 10 Q. Okay. So can you give us an overview of
- 11 what percentage of your time was devoted clinical,
- interventional, things like that?
- A. Well, I was -- I've always been in
- 14 private practice, and private practice, you kind of
- have to do what the hospital needs. So I -- I
- pretty much did the full repertoire of diagnostic
- 17 radiology, and I did interventional radiology as
- well.
- Q. Could you give any estimate as to the
- 20 percentage of your time between those two practice
- 21 areas, 50 percent clinical, 50 percent
- interventional, 90/10?
- A. It varied. It varied upon our group's
- manpower needs, the hospital's needs, our shaping
- of the practice. But I prob -- I did about

- anywhere from a low of about 30 percent to a high
- of about 50 percent.
- Q. Of what?
- 4 A. Interventional, yeah.
- 5 Q. Did that include placing IVC filters?
- 6 A. It did, yes.
- 7 Q. I think I read somewhere in your
- 8 background that you also have some training or
- 9 experience in neuroradiology?
- 10 A. I do.
- 11 Q. Can you describe that for the jury?
- 12 A. Neuroradiology is also a ten-year
- 13 certificate. I took a subspecialty board exam in
- 14 neuroradiology when I was in Ohio, and I did not
- pass the first time. But I passed the second time.
- And I just took the test last April 3rd, two or
- three days ago. I don't know if I've passed.
- 18 O. Good luck --
- 19 A. Thank you.
- Q. -- with that. Could you tell the jury or
- give some examples of what the practice in
- 22 neuroradiology involves?
- A. Well, it's head, neck, and spine imaging.
- The head and neck, brain and spine imaging, and
- diseases related to those parts of the body.

- 1 Q. Is there any interventional treatment you
- do in the head and neck area?
- A. There is -- there's some minor
- 4 procedures, yeah.
- 5 O. Which would involve what?
- 6 A. Diagnostic lumbar punctures, epidural
- ⁷ blocks, a rare biopsy. It's not that procedurally
- 8 oriented, it's more imaging.
- 9 Q. I want to now focus in on your use of
- 10 medical devices up to and particularly IVC
- 11 filters. But before we focus in on IVC filters,
- can you explain to the jury -- or do you use other
- 13 types of medical devices: catheters, stents,
- things like that in your practice?
- 15 A. All the above.
- Q. Do you have contact with representatives
- 17 from manufacturers of those devices?
- 18 A. Yes.
- 19 Q. Do they come and present some products to
- 20 you?
- A. Sometimes.
- Q. Focusing on IVC filters, am I correct
- that you've been implanting IVC filters as far back
- 24 as the early '90s?
- 25 A. Yes.

- Q. And that remained roughly steady
- throughout your tenure up through and including
- 3
- 5 A. Yes.
- Q. When do you recall starting to use Bard
- 7 IVC filters?
- A. I don't specifically know. But I would
- 9 say a long time.
- Q. Were you using those, meaning Bard IVC
- 11 filters, when you were practicing medicine in Ohio?
- 12 A. Yes, I believe.
- Q. Do you recall which filter?
- 14 A. No. The names have changed.
- Q. Do you recall the name of a filter called
- the Simon Nitinol filter, or SNF?
- 17 A. Yes.
- Q. Did you use that filter for any period of
- 19 time?
- A. I might have.
- Q. Do you currently still implant IVC
- 22 filters?
- 23 A. I do.
- Q. Do you currently still use Bard IVC
- 25 filters?

- 1 A. Yes.
- Q. Do you currently ever implant permanent
- 3 as opposed to retrievable IVC filters?
- 4 A. Recently, almost all of the manufacturers
- 5 have veered towards the temporary filters.
- 6 Q. And has recently your practice been to
- 7 implant most all -- always a retrievable filter?
- 8 A. Yes.
- 9 Q. When you were implanting a permanent
- 10 filter, do you recall any particular brand you
- 11 used?
- 12 A. I forgot the names of the brands that are
- permanent. There's so many of them.
- Q. Is it fair to say,
- there was more than one brand of IVC filter?
- 16 A. Yes.
- 17 Q. There were competitors in the
- 18 marketplace?
- 19 A. Yes.
- Q. That included in the permanent filter
- 21 market, true?
- 22 A. Yes.
- Q. And the retrievable filter market?
- 24 A. Yes.
- Q. You, as a practicing physician, had a

- 1 choice about which IVC filter to recommend to your
- patients?
- 3 A. Yes.
- 4 Q. You also had a choice as to whether or
- 5 not to recommend to a patient if they should even
- 6 have an IVC filter or not?
- 7 A. Yes.
- Q. That is -- that type of advice is part of
- 9 the practice area of interventional radiology?
- 10 A. Yes.
- 11 Q. As part of your -- well, before I get
- there. Could you give the jury a brief explanation
- as to the function of an IVC filter based on your
- 14 training and experience.
- A. It's designed to prevent a blood clot
- 16 from a lower extremity or pelvis to going directly
- to the lungs. It prevents pulmonary emboli.
- Q. Where in the body is it placed?
- 19 A. It can vary. But it's customary to put
- the filter at or below the renal veins.
- Q. In what part of the anatomy? Where does
- 22 it go?
- A. In the inferior vena cava.
- Q. As part of your training and experience,
- did you become familiar with the anatomy of the

- 1 inferior vena cava?
- A. Yes.
- Q. Did you also visualize the inferior vena
- 4 cava when you were implanting IVC filters?
- 5 A. Yes.
- Q. Is the -- well, why don't you describe
- 7 for the jury the main function or what function the
- 8 inferior vena cava performs.
- 9 A. If -- the inferior vena cava is a vein
- that helps blood from our lower extremities and our
- 11 pelvis recirculate back in our body.
- Q. Can it expand with varying pressures?
- 13 A. Yes.
- Q. Does it expand with varying pressures?
- 15 A. Yes.
- Q. Is that well known within the medical
- 17 community?
- MR. LEIB: Well, let me just interject.
- 19 At this point he's being called as a fact witness,
- he's not being called as an expert witness. It's
- 21 asking him to render an opinion as to what is or
- isn't known within the medical community. I view
- that as calling for an expert opinion beyond the
- scope of his care and treatment of this patient.
- 25 And he has a privilege under

1 Wisconsin law, it's called -- referred to as the 2. Alt, A-L-T, privilege. And therefore, I'll 3 instruct him not to answer as to any questions that 4 are asked here today and -- you know, we'll 5 obviously take them one by one. But he has not agreed to present himself here today as an expert 6 7 So I'll be instructing him if I feel the 8 question invades that privilege. 9 BY MR. SAELTZER: Okay. Doctor, based on your training and 10 11 experience as of _____, was it your 12 understanding that the inferior vena cava expands 13 and contracts with normal respiratory and -- and 14 heart function? 15 Α. Yes. 16 Q. Moving to 21 Q.

- 1 Q. Do you know, based on the custom and
- 2 practice of the medical group and hospitals where
- you were practicing at that time, if you would have
- 4 had input into that decision or if you would have
- been directed by somebody else which filter to use?
- A. I was comfortable with the product, and
- 7 it was available.
- Q. Fair to say, as the implanting treating
- physician, that you had the discretion to use the
- 10 IVC filter you believed was the safest and most
- 11 effective for your patient?
- 12 A. Yes.
- Q. Am I also correct that you would never
- 14 put in an IVC filter unless you believed it was the
- best performing, most effective filter for your
- 16 patient?
- 17 A. No.
- MR. LEIB: You're asking him --
- MS. DALY: Object to the form.
- MR. LEIB: Yeah, you're asking him in
- regard to your client, Ms. Herd?
- MR. SAELTZER: I was asking about his
- 23 practice as of the time period of
- and the thought process he goes through when
- selecting which filter to use.

- 1 MR. LEIB: Okay.
- MS. DALY: Object to the form.
- 3 BY MR. SAELTZER:
- Q. At least that was the hope of what I was
- 5 trying to ask. Sometimes when I'm asked that, I
- 6 say that's what I was trying to ask. I'm not sure
- 7 I succeeded. So what I'm getting at, or want the
- given jury to understand, is the thought process, the
- 9 judgment, the clinical judgment and how you
- 10 exercised that clinical judgment back in
- Are you following me, Doctor?
- 12 A. Sure.
- Q. Okay. Because you're presented with a
- 14 history from a patient; right?
- A. Uh-huh.
- 16 Q. Is that correct?
- 17 A. Yes.
- 18 O. You can review medical records and
- imaging studies about the patient's condition;
- 20 right?
- 21 A. Yes.
- Q. You want to gain an understanding, to the
- extent you feel is necessary, of the patient's
- 24 condition to make treatment recommendations?
- 25 A. Yes.

- Q. And then you also apply your knowledge as
- to what possible procedures or devices are
- 3 available to treat that condition; right?
- 4 A. Yes.
- MS. DALY: Objection. Objection,
- 6 leading.
- 7 BY MR. SAELTZER:
- Q. And Doctor, in coming and exercising your
- 9 clinical discretion, do you perform a risk-benefit
- 10 analysis?
- 11 A. I get an informed consent, which includes
- 12 risks, benefits, and alternatives.
- Q. When you are choosing which IVC filter to
- implant in a patient, can you describe for me what
- thought process you go to as to which filter you
- 16 select from the various options that are out there
- in the marketplace?
- MR. LEIB: We're talking about in or
- as a custom and practice pertaining to
- your client, Lisa Herd?
- MR. SAELTZER: Yes, in and around
- 22
- THE WITNESS: I look for any filter
- that's FDA approved, that I'm familiar with
- 25 placing.

BY MR. SAELTZER: 1 2. Back , was it your Ο. understanding that all FDA-cleared IVC filters had 3 4 the same performance? They all performed the same? 5 MS. DALY: Object to the form, it's an 6 expert -- it's an expert question. 7 MR. LEIB: Frankly, I didn't hear it that 8 way, and I want to be evenhanded on it. And he's 9 not here as an expert, and he's not presenting 10 himself, but can you elaborate why you felt that 11 was an expert question so I can consider whether or 12 not he should exercise his privilege on it? 13 MS. DALY: Yes. The way that I heard the 14 question was he's being asked about his opinion 15 about various filters that were in the market at 16 the time. To me, that's an expert question. 17 MR. LEIB: Maybe we could hear the 18 question back. 19 COURT REPORTER: was it your understanding that all 21 FDA-cleared IVC filters had the same performance? 22 They all performed the same?" 23 MR. LEIB: Yeah, I -- I don't think it's 24 privileged because it was tethered to , and I 25 viewed the question as pertaining to generally his

- 1 custom and practice at the time that he implanted
- on Mr. Saeltzer's patient -- client. So I didn't
- yiew it as invading privilege. It was historical
- 4 as to his thought process. So that's why I didn't
- 5 assert a privilege, and I wouldn't instruct him.
- 6 MS. DALY: I'm sorry, just again note my
- ⁷ objection.
- MR. LEIB: Yeah, okay. And Taylor, I
- 9 just didn't want to -- the reason why I asked you
- 10 to elaborate because I -- you know, I assume that
- 11 you're going to be asking some questions, and I
- want to be, as I say, evenhanded as to asserting
- 13 the privilege to make sure that I understand what
- 14 your objection is so if other objections come down
- the pike during your questioning, you know, I'll
- instruct him evenly between both parties.
- MS. DALY: Thank you.
- 18 BY MR. SAELTZER:
- 19 Q. Do you have the question in mind, Doctor?
- Would you like it read back to you?
- A. I'm sorry, what am I being asked?
- Q. That tells me we should probably read you
- the question. So we'll have the question read to
- you, Doctor.
- 25 COURT REPORTER: "Back in

- was it your understanding that all
- FDA-cleared IVC filters had the same performance?
- 3 They all performed the same?"
- 4 THE WITNESS: I think that they -- they
- 5 were -- they were all very comparable.
- 6 BY MR. SAELTZER:
- 7 Q. Did you believe that they were all
- 8 comparable in terms of risk of complications, such
- 9 as migrations or fractures?
- 10 A. Yes.
- 11 Q.

- MR. LEIB: Yeah, and I think that does
- call for an expert opinion, and I would instruct
- 19 him not to answer. And I would invite you to
- re-frame the question to avoid invading the
- 21 privilege and --
- MS. DALY: Join in the objection.
- 23 BY MR. SAELTZER:
- Q. So Doctor, I want to go -- again, we'll
- go back, we time travel back to your thought

- 1 process in exercising your clinical judgment back
- 2 to Do you have that time
- 3 period in mind?
- 4 A. Sure.
- 5 Q. Okay. And if the IVC filter,
- 7 carried with it a significant potential for serious
- 8 injury or death, and the company knew about that,
- 9 you would have wanted them to tell you that, fair
- 10 to say?
- MR. LEIB: Let me object --
- MS. DALY: Object.
- MR. LEIB: -- I do think --
- MS. DALY: Object to the form.
- MR. LEIB: Yeah, I think it's a
- 16 hypothetical question, and I think it does draw
- upon his expertise to be able to -- to know what or
- what isn't significant, what -- you know, what
- 19 knowledge was known. And because he doesn't recall
- this patient, to be able to apply it to a patient
- is calling for -- it's a hypothetical question and
- I think it does invade a privilege in that regard.
- 23 So I would instruct him not to answer.
- MR. SAELTZER: Well, my question -- this
- jury's going to hear evidence in this case and is

- 1 going to wonder what doctors rely upon, not lawyers
- 2 arguing in a court of law. But they're going to
- have to determine in this case, with this doctor,
- 4 what type of information was important or not
- 5 important to that doctor based on the way this
- 6 doctor applies his clinical judgment.
- And so I'm asking this doctor, who
- 8 implanted this filter, for his state of mind as to
- 9 the type of information at that time he considered
- relevant to his clinical judgment. He's the only
- one who made the decision to implant this filter,
- and so his state of mind, not his opinion, but his
- 13 state of mind and custom and practice at that time
- is -- isn't an expert opinion, it's very relevant
- to what happened.
- MR. LEIB: And --
- MS. DALY: I'm going to object to the
- 18 leading nature of the question. And if you just
- want to ask him what did he rely on at that time,
- that would probably be a nonleading question.
- MR. LEIB: Okay. And just so we
- understand my role here, my only purpose is to
- instruct him regarding privilege and representing
- the witness; I can't assert or argue leading,
- foundational, or anything else. But his

- decision-making regarding this patient, we know he
- doesn't remember the patient, and if the question
- 3 is what was your custom and practice regarding what
- 4 information you would use to make decisions
- 5 regarding this patient, that I don't have a problem
- 6 with, as long as it's asked in that form.
- 7 And if you recall, then you should
- 8 indicate you recall. And if you don't recall, you
- 9 should indicate you don't. He doesn't want you to
- 10 quess at what the answers are. So -- so you gotta
- listen closely to the question. So could I ask
- 12 that you ask the question within a context so I
- don't have an issue with privilege on it?
- 14 BY MR. SAELTZER:
- Q. Doctor, based on your custom and
- 16 practice, if the company, Bard, knew that the
 - that is the
- 19 type of information, based on your custom and
- practice, you would have wanted to know about?
- MS. DALY: Objection, leading, and a
- 22 hypothetical.
- MR. LEIB: It's definitely a hypothetical
- question, and the expertise that's required is to
- know what you're talking about as to what's

- 1 significant or not. And unless he has some
- 2 recollection and can state the answer
- 3 historically as opposed to giving a new opinion
- 4 now -- 'cause a new opinion now is privileged in
- 5 this. So unless you can answer that question
- 6 historically as to what your thought process was in
- 7 if this would be giving a new opinion as of
- 8 today, then I would instruct you not to answer.
- 9 THE WITNESS: If the product is FDA
- 10 approved and I'm comfortable with it, I don't
- usually hesitate.
- 12 BY MR. SAELTZER:
- Q. What knowledge, if any, do you have of
- 14 how the Bard G2X filter received FDA clearance?
- 15 A. I do not know.
- Q. At the time you implanted this filter,
- did you believe it had gone through full clinical
- trials to obtain FDA approval?
- 19 A. I'm guessing, yes.
- Q. At least that was your state of mind back
- 21 then?
- 22 A. Yes.
- Q. Are you aware of an alternate FDA
- 24 approval process called a 510(k) clearance?
- 25 A. No.

- Q. Are you aware of an FDA process that
- 2 allows an abbreviated clearance if the company
- proves the product is substantially similar to a
- 4 prior product that's already been cleared?
- 5 A. No.
- 6 Q. Fair to say your state of mind when you
- 7 implanted this G2X filter is that it was as safe
- 8 and effective as the competitors' filters that were
- 9 on the market at that time?
- MS. DALY: Object to the form, leading.
- MR. LEIB: I think you already asked and
- answered that, actually. , when this
- 13 was --
- 14 THE WITNESS: Yes. My answer's yes.
- 15 BY MR. SAELTZER:
- Q. Part of your responsibilities as the
- 17 physician who was
- to explain to her the risks associated with the
- 19 filter; am I correct?
- 20 A. Yes.
- MS. DALY: Objection, leading.
- 22 BY MR. SAELTZER:
- Q. Did you receive training on that
- obligation in medical school, your residency, and
- 25 also in your fellowship?

- 1 A. Yes.
- Q. Is part of obtaining informed consent
- 3 included in the training to become an
- 4 interventional radiologist?
- 5 A. Yes.
- 6 O. And to become a doctor?
- 7 A. Yes.
- Q. Getting to your custom and practice
- was it your practice to inform the patient of
- 10 all known risks, meaning risks you knew about that
- were associated with an IVC filter you were
- recommending be implanted in that patient?
- MR. LEIB: Let me just object, it's not
- the proper standard under which the doctor would
- have been practicing So I guess I'll let
- him go ahead and answer the question as long as it
- isn't construed presently, or at some later date,
- as some waiver of a privilege. Is that acceptable
- 19 to you?
- MR. SAELTZER: Sure.
- MR. LEIB: Taylor, is that acceptable to
- 22 you?
- MS. DALY: Yes.
- MR. LEIB: Go ahead.
- THE WITNESS: Could you repeat the

question? 1 2. MR. SAELTZER: Let me have the reporter 3 read it back to you, Doctor. 4 COURT REPORTER: "Getting to your custom 5 and practice was it your practice to 6 inform the patient of all known risks, meaning 7 risks you knew about that were associated with an 8 IVC filter you were recommending be implanted in 9 that patient?" 10 THE WITNESS: No, we don't -- we 11 customarily talk about common things. We don't 12 want to be excessively burdening with all risks. 13 BY MR. SAELTZER: 14 , would you have disclosed Ο. 15 any risk associated with the IVC filter that -- to 16 the patient that you believe presented a serious 17 risk of injury or death? 18 There was a risk that I would not be able Α. 19 to deploy it. There was a risk that the anatomy 20 wouldn't lend itself to deployment. There was a --21 she has the right -- he or she has the right to 22 refuse the filter in option of other medical 23 therapies, anticoagulation. The benefits are that 24 the filter does -- does prevent pulmonary emboli. 25 Ο. At the time you er

- did you understand that one of the
- 2 risks associated with the filter was that it could
- migrate from the location you implanted in?
- 4 A. I was, yes.
- 5 Q. Were you aware that one of the risks was
- 6 that the filter could fracture?
- 7 A. I was aware. I think it's exceedingly
- 8 rare.
- 9 Q. Were you aware that the filter could
- 10 perforate the cava wall?
- 11 A. I think that that's a hypothetical.
- Q. What do you mean by that? It's so rare
- it's a hypothetical, or --
- 14 A. Yes.
- 15 Q. Okay. I thought I understood it; I
- wasn't quite positive. So getting back to those
- 17 risks of perforation. You've just explained to me
- 18 your state of mind as to the frequency, and you
- also explained to this jury that the risk of
- fracture was, I think in your words, exceedingly
- 21 rare?
- 22 A. Yes.
- Q. Did you have any understanding as to the
- 24 frequency at which the G2X was at risk to migrate?
- 25 A. No.

- Q. In terms of complications that could be
- 2 associated with this G2X filter, had you formed any
- 3 clinical impression back as to which of the
- 4 potential complications were more concerning or
- 5 presented a greater risk to the patient than
- 6 others?
- 7 A. Yes.
- 8 Q. What were those?
- 9 A. Fracture with migration.
- 10 Q. That would be the most -- I take it you
- listed that first, so that would be the most
- 12 serious?
- 13 A. I assume so, yes.
- Q. When you say "fracture with migration"
- and -- do you mean embolization of the fracture
- 16 fragment?
- 17 A. Yes.
- Q. Okay. At the time you
- did you believe that that
- filter presented roughly the same risk of
- 21 fracturing and embolizing as competitor filters in
- the market at that time?
- 23 A. Yes.
- Q. Same question with migrations, same
- 25 answer?

- 1 A. Yes.
- 2 Q. Same question with perforations, same
- 3 answer?
- 4 A. Yes.
- 5 Q. And back in your practice, all
- 6 other things being equal for a medical device you
- you would were going to implant in a patient, you would
- 8 choose the one that had the lowest complication
- 9 rate that you were aware of that?
- 10 A. That I was aware of.
- MS. DALY: Objection, leading. Sorry,
- 12 Doctor.
- 13 BY MR. SAELTZER:
- Q. Did we get the answer? Now, you've
- described for the jury some of your understanding
- 16 as to how frequent these complications would occur.
- Where did you obtain that understanding from?
- 18 A. I think kind of just a general knowledge,
- 19 textbooks, going to meetings, stuff like that.
- Q. Conversations with colleagues, I take it?
- 21 A. Yeah. But mostly published literature.
- Q. What sources of published literature did
- you look at and rely upon back to gain
- information about complication rates with IVC
- filters or similar products?

- 1 A. Nothing specifically. Maybe just a
- 2 general feel for what was happening in the market.
- Q. Are you members of any journals or
- 4 publications?
- 5 A. No.
- Q. Are you members of any societies,
- 7 professional societies?
- A. I am a member of the Society of
- 9 Interventional Radiology.
- 10 Q. And what's your role within that
- 11 organization?
- 12 A. Pay dues, and if I can get away, I might
- go to a meeting, which is pretty rare.
- Q. Do you recall, prior or at --
- let's say at the time of if there
- was a Bard sales representative you were
- 17 interacting with?
- A. I do not recall.
- Q. Does the name, a Mr. Chris
- 20 Siller, S-I-L-E-R, sound familiar?
- 21 A. No.
- Q. Do you recall ever having any
- discussions, at any time prior to
- with any Bard sales representative?
- A. Specifically, no.

- Q. Was it a part of your custom and practice
- 2 to occasionally meet with sales representatives of
- medical device companies?
- 4 A. Rarely.
- 5 Q. Do you know if you ever met, prior to
- with any Bard sales representative?
- 7 A. I probably did, but I don't specifically
- 8 recall.
- 9 Q. Would you obtain information from the
- 10 product -- about the product from a sales
- 11 representative when you met with them?
- MS. DALY: Object to the form, leading.
- 13 THE WITNESS: Can you repeat the
- 14 question?
- 15 BY MR. SAELTZER:
- Q. Sure. I'm wondering when you met with
- them, it was for professional reasons, I was
- 18 assuming, or was it personal?
- 19 A. It was professional.
- Q. Okay. The professional reason --
- A. (Witness laughing.)
- Q. I apologize for asking questions that are
- very basic. The professional meeting would be to
- learn about the product --
- 25 A. Yes.

- Q. -- from the sales representative?
- MS. DALY: Object to the form as leading.
- THE WITNESS: Yes.
- 4 BY MR. SAELTZER:
- Q. Was it your expectation that that sales
- 6 representative was providing you full and accurate
- ⁷ information about any complications they were aware
- 8 of with that product?
- 9 A. That I can't --
- MS. DALY: Objection.
- 11 THE WITNESS: I can't answer that.
- MS. DALY: Excuse me, Doctor. Objection,
- leading and lack of foundation, since he doesn't
- 14 recall the meeting.
- 15 BY MR. SAELTZER:
- Q. Do you recall if you used the Bard
- 17 Recovery filter, which was the predecessor to the
- 18 G2?
- 19 A. I believe I did.
- Q. Did anyone from Bard ever reach out to
- you and inform you that after the Recovery was
- placed on the market, they undertook an internal
- 23 remedial action plan?
- 24 A. No.
- Q. Did anybody from Bard ever inform you

- 1 that the result of their internal remedial action
- 2 plan was that a safety alert or warning should be
- given about the Recovery filter?
- 4 A. I do not --
- 5 MS. DALY: Object to the form.
- 6 THE WITNESS: I do not specifically
- 7 recall.
- 8 BY MR. SAELTZER:
- 9 Q. Do you recall ever receiving a safety
- 10 alert or warning from Bard about any of its IVC
- 11 filters prior to ?
- 12 A. I don't recall.
- Q. Did anyone from Bard ever inform you that
- in terms of complication rates, its internal
- analysis showed the Recovery performed unfavorably
- when compared against the competition?
- 17 A. No.
- MS. DALY: Object to the form.
- 19 BY MR. SAELTZER:
- Q. What was your answer, Doctor?
- 21 A. No.
- Q. Did anybody from Bard ever inform you
- that back in December of 2004, its analysis had
- showed that the Recovery filter migrated more
- frequently than the Simon Nitinol filter?

- 1 MS. DALY: Object to the form and not 2 relevant to Mrs. Hyde. 3 THE WITNESS: No. 4 BY MR. SAELTZER: 5 Did anybody from Bard, prior to Ο. 6 , ever tell you that the Recovery 7 filter migrated three times the industry average? 8 Α. No. 9 MS. DALY: Same objection. 10 BY MR. SAELTZER: 11 Is that the type of information you would 0. 12 have found useful in your clinical practice to 13 determine which filter to use? 14 MR. LEIB: Well --15 MS. DALY: Object to the form, it's an 16 expert opinion. 17 MR. LEIB: Yeah, I think that is an 18 expert opinion. It's a hypothetical. Yeah, so 19 I'll instruct you not to answer that question.
- MR. SAELTZER: Just so the record's
- clear, I'm asking him for his state of mind as to
- what information, as the treating physician, he
- would consider important in making a decision about
- which filter to use.
- MR. LEIB:

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1
              MR. SAELTZER: Yes.
 2.
              MR. LEIB: Yeah, that wasn't your
 3
    question, though. You're asking him for a present
 4
    opinion as to whether or not something would have
 5
    been helpful to him in the past. That is calling
 6
    for an expert opinion. If you --
 7
              MS. DALY: Which --
 8
              MR. LEIB: Hold on.
 9
              MS. DALY: -- which -- let me --
10
    if I could add for the record, which also related
11
    to a filter that was a predecessor to the filter in
12
    the Hyde case.
13
              MR. LEIB: Yeah, I'm not apprised of the
14
    different filters, so I'll leave those objections
15
    to counsel. But I'd invite you to rephrase the
16
    question. But I think the way you phrased it, it
17
    is invading his privilege, that's why I instructed
18
    him not to answer.
19
    BY MR. SAELTZER:
20
               Is the information that Bard determined
         0.
21
    its Recovery filter migrated three times more than
22
    the industry average the type of information you
23
    would have found useful when you were making your
24
    decisions about which filter to implant back in
```

?

25

- 1 MS. DALY: Same objections.
- MR. LEIB: He doesn't want you to
- 3 speculate. If you have to guess, you have to tell
- 4 him. If you -- based upon the information you've
- been given, if you can state back in you can
- 6 go ahead and historically tell him that.
- 7 THE WITNESS: Right or wrong, I felt that
- 8 the risks for all of the FDA-approvable devices
- 9 were -- were reasonable and customary, and that I
- 10 probably wouldn't have deferred or postponed the
- 11 filter placement in a patient who I felt really
- 12 needed it.
- 13 BY MR. SAELTZER:
- Q. As I'm understanding your answer, right
- or wrong, you assumed that the complication rates
- among the FDA cleared or approved IVC filters was
- 17 roughly equivalent?
- 18 A. Yes.
- 19 Q. If you had learned differently, that
- would be the type of information that you would
- have used in your clinical practice, true?
- MS. DALY: Same objections.
- THE WITNESS: I tend to trust the FDA
- more than individual companies.
- 25 BY MR. SAELTZER:

1 Understanding that you have some 2. more trust of the FDA than individual companies, if you actually learned that the complication rates 3 4 among filters was not equivalent, even though they 5 had all been cleared, that's the type of 6 information, as a treating doctor, you would have 7 been interested in and considered -- at least considered when making your treatment decisions? 8 9 MR. LEIB: Well --10 MS. DALY: Objection. Same objection as before, leading, and now it's argumentative. 11 12 MR. LEIB: 25

- 1 BY MR. SAELTZER:
- 2 Q. Based on your practice of medicine back
- when you're making the decision about
- 4 which device to implant in a patient's body, you --
- is it your testimony that you wouldn't be concerned
- 6 with how frequently those fail?
- 7 A. It was my --
- 8 MS. DALY: Same objection.
- 9 THE WITNESS: It was my understanding
- that the complication rates were low. And, as a
- 11 physician, you have to look at the big picture.
- 12 And I think that the -- all of the devices were
- meeting the expectations of the FDA, and I didn't
- see any deciphering thing to persuade me one way or
- the other.
- 16 BY MR. SAELTZER:
- Q. Did you have any understanding, back in
- 18 , as to the percentage of expected
- 19 failures for the G2X filter in terms of migrations
- 20 or fractures?
- A. No specific. Rare.
- Q. Was it your understanding, back in
- that the migration rate could be as high as ten
- 24 percent?
- 25 A. No.

- Q. Was it your understanding that the
- 2 migration rate was lower than ten percent?
- A. My understanding was that it was less
- 4 than ten, but I don't -- my understanding may be
- 5 wrong.
- 6 Q. Did anybody from Bard ever inform you,
- 7 prior to ______, that as early as 2004,
- 8 Bard had determined that the reports of death for
- 9 the Recovery filter were 4.6 times higher than
- 10 reporting rates for all other filters?
- 11 A. No.
- MS. DALY: Objection as leading and not
- 13 relevant to Mrs. Hyde's case.
- 14 BY MR. SAELTZER:
- Q. Did anybody at Bard ever inform you,
- prior , that as early as 2004, Bard had
- determined that the Recovery filter migration rates
- were 4.4 times higher than the reporting rates of
- migrations for all other filters?
- MS. DALY: Same objections.
- THE WITNESS: I don't know.
- 22 BY MR. SAELTZER:
- Q. You don't recall ever learning that
- 24 before you decided?
- 25 A. No.

How about 5.3 times more likely to 1 Ο. 2 fracture? 3 MS. DALY: Same objections. 4 THE WITNESS: Same answer. 5 BY MR. SAELTZER: 6 Ο. Before you you believed that Bard had subjected that filter to a clinical trial? 9 I knew it was FDA approved. At least I'm Α. 10 pretty sure it was. 11 Does that mean you believed that part of 0. that process would have included a clinical trial? 12 13 I don't know exactly how the FDA goes 14 about their business. 15 Did you have an expectation, as of Q. 16 19 I don't really know if I had an Α. 20 expectation. I just -- if it was FDA approved, it 21 was --22 Q. Good for you? 23 Α. Yeah. Had you ever heard of or been aware of a 24

clinical trial back in the early 2000 time period

25

- 1 by a radiologist named Murray Ash for the Recovery
- 2 filter?
- 3 A. No.
- 4 Q. You mentioned you tend to trust the FDA
- 5 more than manufacturers. Why is that?
- 6 A. It's a third party.
- 7 Q. An unbiased third party?
- 8 A. Yeah.
- 9 Q.
- did anybody at Bard ever inform you
- 11 that back in 2004, they had determined the Recovery
- 12 filter, at a 95 percent confidence rate, had a
- 13 statistically significant difference in the rate of
- death than its competitors?
- MS. DALY: Object to the form and object
- 16 to the relevance.
- MR. LEIB: Let me just ask. This
- 18 Recovery device, was that something that he
- utilized with this patient?
- MR. SAELTZER: He used what was a
- 21 substantially similar FDA-approved filter, the G2X.
- MS. DALY: Let me say this. The G2X is
- not the Recovery filter, it is actually a third
- generation of Bard filter. So counsel's saying
- it's similar, that's not a good description.

1 MR. LEIB: Can I have the question again? 2. COURT REPORTER: did anybody 4 at Bard ever inform you that back in 2004, they had 5 determined the Recovery filter, at a 95 percent 6 confidence rate, had a statistically significant 7 difference in the rate of death than its 8 competitors?" 9 THE WITNESS: I do --10 MS. DALY: Same objection. 11 THE WITNESS: I don't specifically 12 recall. 13 BY MR. SAELTZER: 14 Let me mark as an exhibit a journal 15 article. We'll mark it as next in order, which I 16 believe is 2128. 17 MR. LEIB: Counsel, I certainly respect 18 your right to mark it. And if the doctor has viewed this article previously, , in 19 20 regards to his care and treatment of the patient, 21 your client, then I think you've laid a foundation 22 which allows you to ask historically about it. 23 he hasn't, then I'm not going to have him answering 24 any questions and reviewing the article. 25 MS. DALY: Can I put something on the

- 1 record too? Which article are you presenting right
- 2 now?
- MR. SAELTZER: This is the Nicholson
- 4 article that we talked about before the deposition
- 5 started, and I mentioned I was going to use.
- 6 MS. DALY: Okay. So I want to put
- 7 this objection on the record. The objection that I
- 8 have is under CMO No. 21, part 383, the plaintiffs
- 9 are required to give out the disclosure of
- documents to be used with the doctor five days
- 11 before the deposition. I have your submitted list;
- it does not have that article on it. And I object
- to the use of the article on the basis that CMO
- No. 21 was improperly complied with. That's my
- objection for the record. Thank you.
- 16 (Exhibit 2128 marked for identification.)
- MR. SAELTZER: Let -- Counsel, would you
- 18 like to see it first?
- MR. LEIB: Yeah, I have not seen this
- 20 before and --
- MR. SAELTZER: I can't ask a foundation
- question, Counsel, unless I show it to him.
- MR. LEIB: Yeah.
- MR. SAELTZER: Why don't we let the
- doctor get through this, and I can ask the question

- 1 if he's seen it before.
- MR. LEIB: Yeah.
- 3 BY MR. SAELTZER:
- Q. And Doctor, you want -- I understand
- 5 there's a time limit that we have today with you?
- 6 Is that right, Doctor?
- 7 A. Yes.
- 8 Q. So maybe everybody can keep that in mind
- when making objections or doing things that could
- tie up the record and prevent the jury from hearing
- 11 the doctor's testimony.
- Doctor, can I just ask you --
- MS. DALY: Doug, excuse me one second. I
- 14 appreciate that, and I appreciate that the doctors
- having the time, but I have got to make my
- objections on the record, and I will do them
- succinctly, and I will do them as form objections,
- but I'm going to make them. Thanks.
- 19 BY MR. SAELTZER:
- Q. Doctor, showing you what's been marked as
- 21 Exhibit 2168 [sic]. Do you recognize, first, the
- journal that it comes from?
- 23 A. No.
- Q. Have you ever seen this article?
- 25 A. No.

- 1 Q. Doctor,
- were you aware that Bard had
- 3 performed a clinical study of the G2 filter called
- 4 the Everest study?
- 5 A. No.
- 6 Q. Did anybody from Bard ever make the
- 7 results of that Everest study available to you?
- 8 A. I don't specifically recall.
- 9 Q. The initial author of the report was a
- doctor, a cardiologist named Dr. John Lehmann. Do
- 11 you know Dr. Lehmann?
- 12 A. I do not.
- Q. Ultimately he was removed as the author
- of the report. Did anybody from Bard ever inform
- you that for the G2 filter study, it had removed
- the author from the report?
- 17 A. I don't recall.
- MS. DALY: Object to the form.
- 19 BY MR. SAELTZER:
- Q. Doctor, if the initial author of that
- 21 report had believed that the results of the Everest
- G2 trial demonstrated that the G2 filter and safety
- profile was not consistent with similarly marketed
- IVC filters, is that the type of information, based
- on the way you practiced medicine , you

would have wanted Bard to let you know about? 1 2. MR. LEIB: Yeah, let me object --3 MS. DALY: Object to the -- object to the 4 form and lack of foundation. 5 MR. LEIB: Yeah, and I believe it invades 6 privilege, and I'll instruct him not to answer. 7 MR. SAELTZER: Again, Counsel, I'm asking 8 for his state of mind. 9 MR. LEIB: No, I understand. But he'd 10 have to review the article in order to determine 11 whether or not it contains information that would 12 be important to him And I'm not going to 13 have him review the article. 14 MR. SAELTZER: The foundation can be 15 proven whether or not the article says that. 16 MR. LEIB: Doesn't matter. You're --17 MR. SAELTZER: Can I --18 MR. LEIB: -- using --19 MR. SAELTZER: Can I please finish? 20 Whether or not or what the article says I'm not 21 asking for his testimony about. I'm asking this 22 treating doctor for the way he practiced medicine 23 and what information he considered, the type of 24 information he considered, And I'm asking him if that type of information had existed, 25

- that would have been something he would have
 factored into his clinical judgment.

 MR. LEIB: You've tethered it to the
 article, that's the problem. The form of the
 - question invades his privilege, and that's why I'm
 - 6 instructing him not to answer.
 - 7 BY MR. SAELTZER:
 - 8 Q.
 - was not performing as well as
 - the other competitors' IVC filters, and it knew
 - 11 that before , is that the type of
 - information you would have considered if Bard had
 - brought that to your attention?
- MS. DALY: Same objection.
- THE WITNESS: I don't particularly pay
- 16 attention to everything that's published or comes
- my way. And so if I had read the article, I -- I
- may or may not have been swayed by its contents.
- 19 BY MR. SAELTZER:
- 20 Q.
- did you believe that it presented a
- greater risk of fracturing than other filters in
- the marketplace?
- 24 A. No.
- Q. At the

- 1 , did you believe it presented a greater
- 2 risk of migration than other filters on the
- 3 marketplace?
- 4 A. No.
- 5 Q.
- did you believe it presented a greater
- 7 risk of perforating the vena cava than other
- 8 filters on the marketplace?
- 9 A. No.
- 10 Q. Did you ever -- strike the question.
- 11 Based on your custom and practice and the knowledge
- 12 you believe you had back in
- you were
- 14 recommending she receive presented a greater risk
- of complication than competitive filters?
- 16 A. No.
- Q. Is that the type of information,
- , that, based on your training and experience,
- would need to be disclosed to a patient to obtain
- informed consent?
- A. I may be wrong, but I would say no.
- Q. You mentioned you looked at some medical
- records to prepare for your testimony today?
- A. I saw a one-page procedural document
- yesterday.

- 1 Q. Have you reviewed any other documents to
- help prepare for today?
- A. About a half-hour before we started.
- 4 MR. LEIB: I showed him the --
- 5 THE WITNESS: Discharge.
- 6 MR. LEIB: -- discharge summary to see if
- 7 that would jog his memory as to this patient. It
- 8 didn't. But you're certainly free to ask him what
- 9 he was shown.
- 10 BY MR. SAELTZER:
- 11 Q. Have you had any conversations to prepare
- 12 for today's testimony with anybody other than your
- 13 attorneys?
- 14 A. I went to a risk management person at
- Wheaton, a nurse, coming from out of state, to try
- to figure out what the nature of this was.
- MR. LEIB: You can leave it at that.
- THE WITNESS: Yeah.
- 19 BY MR. SAELTZER:
- Q. I'm not interested in risk management or
- 21 any conversations you may have had with your
- 22 attorney. I'm wondering, have you had any
- 23 conversations with anybody from the plaintiffs --
- representing the plaintiff in this case, Ms. Hyde?
- A. Did I have any conversations? What

- 1 was -- repeat the question.
- Q. Sure. I think I can do it without having
- 3 her reread it.
- 4 A. Sure.
- 5 Q. Did you have any conversations with any
- 6 attorneys who told you they were representing
- 7 Ms. Hyde before coming into this room and giving
- 8 testimony today?
- 9 A. Yes.
- Q. Who did you speak with?
- 11 A. Somebody from a law firm in either
- 12 California or Arizona.
- Q. What did you speak about?
- 14 A. Am I David Henry, and would I be
- available to give a deposition.
- Q. Anything substantive about the filter or
- your knowledge of the filter or --
- 18 A. I didn't know it was -- what it was even
- 19 related to until they sent me two letters. One I
- think may have referred to -- one of the two may
- 21 have referred to IVC filter.
- Q. Did you have any conversations with any
- 23 attorneys or representatives from Bard?
- 24 A. No.
- Q. So what I probably think is best is the

- 1 reporter's been going for an hour, you've been
- testifying for an hour, we can take a quick
- two-minute break here, and then I'm going to come
- 4 back in and wrap up with questions about the
- 5 procedure and your interactions with Ms. Hyde. And
- 6 then Bard's counsel may also have some questions as
- 7 well.
- MR. LEIB: Okay, let's take a few minute
- 9 break.
- THE VIDEOGRAPHER: Going off the record
- 11 at 11:27. Resume on media two.
- 12 (Break taken.)
- THE VIDEOGRAPHER: We're back on the
- 14 record at 11:41, media number two.
- MR. SAELTZER: Okay. Just before we get
- to the questions, Doctor, I did want to put on the
- 17 record: It's my understanding, Counsel, I had told
- 18 you that I presented a confidentiality agreement,
- and I had some documents, HHEs, fracture studies,
- 20 internal Bard documents that I was going to review
- with the witness. But it's my understanding that
- you're instructing the witness not to answer those
- 23 type of questions?
- 24 MR. LEIB: Yes. Unless those were
- documents that he reviewed in the care and

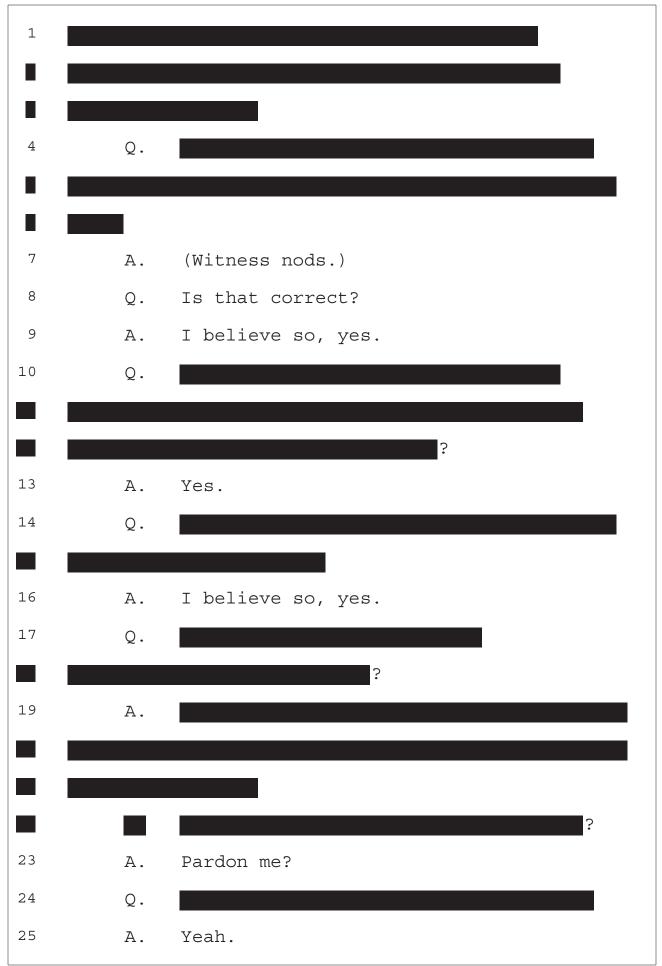
- 1 treatment of this patient. And I understand that
- they were not -- these things were not available.
- 3 So yes, I'm instructing him not to answer. I
- 4 believe it's calling for an expert opinion.
- MR. SAELTZER: You threw one thing in
- 6 there which I want to clarify, which is they're not
- 7 available to him. They're certainly not part of
- 8 his care and treatment. They're records that
- 9 predate the Bard documents that predate his care
- and treatment. So they existed, but I don't think
- 11 he saw them.
- MR. LEIB: Okay. I mean --
- MR. SAELTZER: So you would instruct him
- 14 not to answer?
- MR. LEIB: Yes.
- MR. SAELTZER: I just wanted to make the
- 17 record clear, because I had a bunch of documents
- 18 here I was going to go through with him, but I
- don't want to waste our time.
- MR. LEIB: It will be the same for
- 21 defense counsel.
- MS. DALY: The documents he's speaking of
- 23 are all internal Bard documents. Would not have
- 24 gone external.
- MR. SAELTZER: And the timeline here

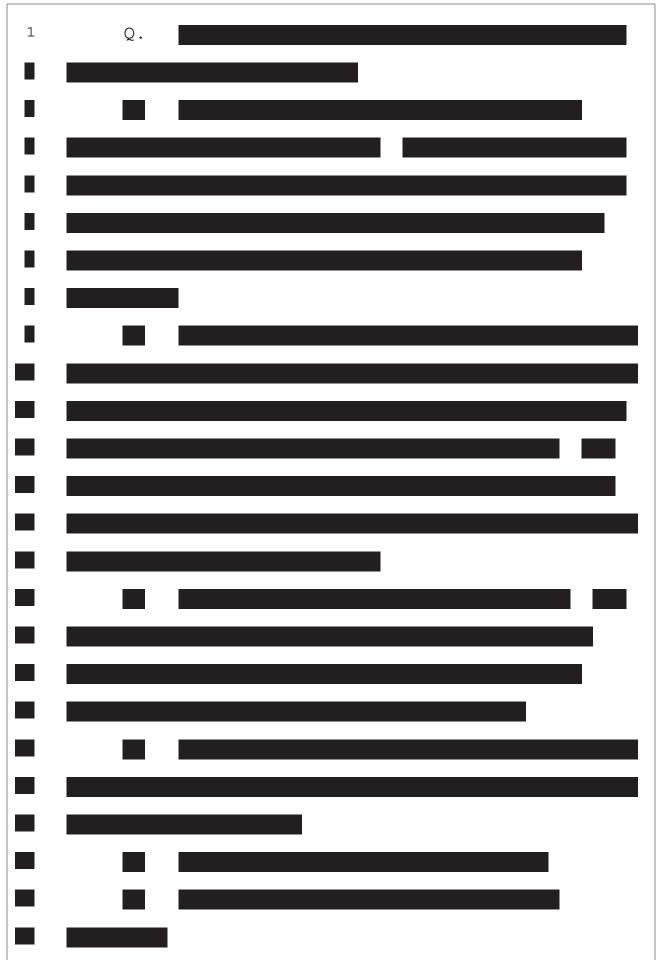
- we're looking at is -- initially it was two hours.
- We've gone a little above that. How much do we
- 3 have to work with here?
- 4 MR. LEIB: Well, he wanted to be out of
- 5 here by noon. He's on vacation currently, so not
- 6 really part of the vacation plan. But, you know,
- ⁷ if we can wrap it up within another hour --
- THE WITNESS: Yes, if we can be done in
- 9 60 minutes, it would be great.
- MR. SAELTZER: Let me get into the
- 11 treatment records and see -- with that
- understanding and limitation, let me get to it.
- MR. LEIB: Okay.
- MS. DALY: Okay, Doug, and if you will
- leave me 30 minutes, that would be great. See what
- 16 you can do.
- MR. SAELTZER: Thank you. Okay.
- 18 (Exhibit 2129 marked for identification.)
- 19 BY MR. SAELTZER:
- Q. We are on the record, so there's no need
- to go back on the record. Doctor, I want to direct
- your attention to what the court reporter has
- marked as Exhibit 2129. Does that contain, as part
- of that exhibit, the medical records that you
- generated pertaining to your care and treatment of

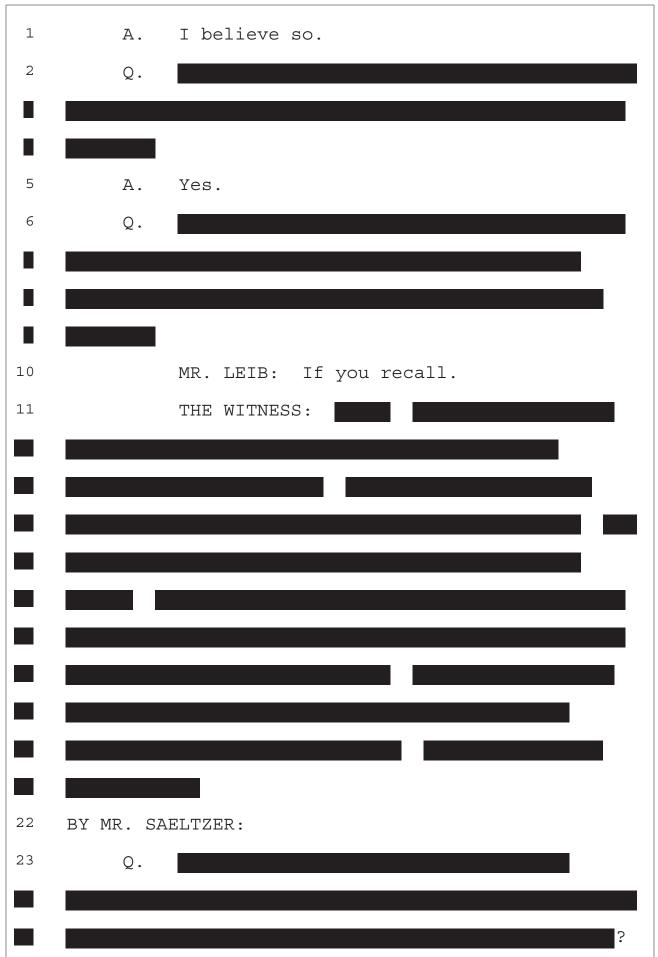
- 1 Ms. Hyde?
- 2 A. It does.
- Q. Is the totality of those records a -- it
- 4 looks like an informed consent document that you
- 5 created.
- 6 A. The hospital created.
- 7 Q. That you used, I should say, for this
- 8 procedure?
- 9 A. Yes.
- 10 Q. Is that your handwriting on the first
- 11 page of 2129?
- 12 A. It is.
- Q. And then if we turn inward, there's
- 14 an -- I'm looking for the procedure notes.
- MR. LEIB: I think it's the third page
- 16 back.
- 17 BY MR. SAELTZER:
- 18 Q. Have you found your procedure note,
- 19 Doctor?
- 20 A. Yeah, it's -- it's --
- Q. If we look at the bottom right corner,
- does the number end in 172?
- 23 A. Yes.
- Q. And it says it's 170 of 290 of the
- 25 medical records?

- 1 A. That's correct.
- Q. How many pages is that? Is it a
- 3 two-page?
- 4 A. It's two-page.
- 5 Q. Is it a dictation, Doctor?
- 6 A. It is.
- Q. Okay. So if I have the informed consent
- 8 and this two-page dictated procedure note, as far
- 9 as you're aware, do I have the entirety of the
- medical records that you created for this patient?
- 11 A. Yes.
- 12 Q. There's also some imaging study at the
- last pages of this exhibit; I think it's the last
- 14 two. Would you have taken imaging or images of the
- position of the filter after you implanted it?
- 16 A. I may have.
- Q. Are you able to tell me if those are the
- 18 picture?
- 19 A. I don't think that these are. This says
- 20 Stanford.
- Q. So these came --
- A. From another institution.
- Q. All right. So let's go through your
- treatment. Feel free, Doctor, to refer to the
- records you have in front of you if you need to to

answer any of my questions. Who referred Ms. Hyde 1 2 to you? 3 Α. I do not recall. 4 Q. 7 Do you recall the reason for your consult? 9 I do not recall, Α. 12 Q. What I want to do is go through your 13 understanding of the patient's history and your 14 thought process for the treatment you recommended. 15 And I want to give you the freedom to do that in a 16 way that is easiest for you with the records and 17 your memory. So could you explain to this jury 18 your understanding of the patient's history? We'll 19 start with that. 20 Α. Yeah.



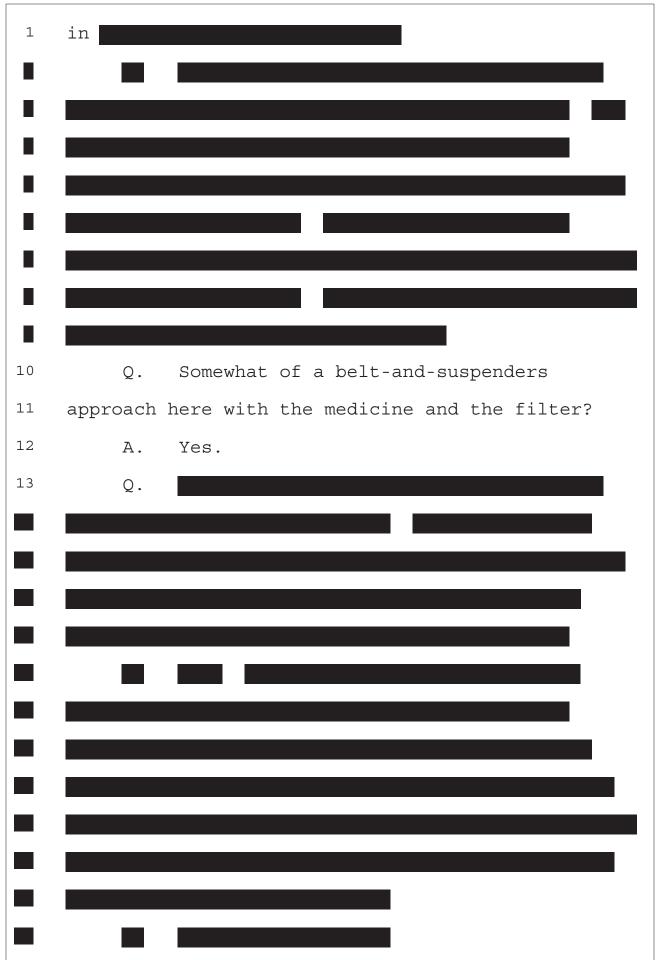


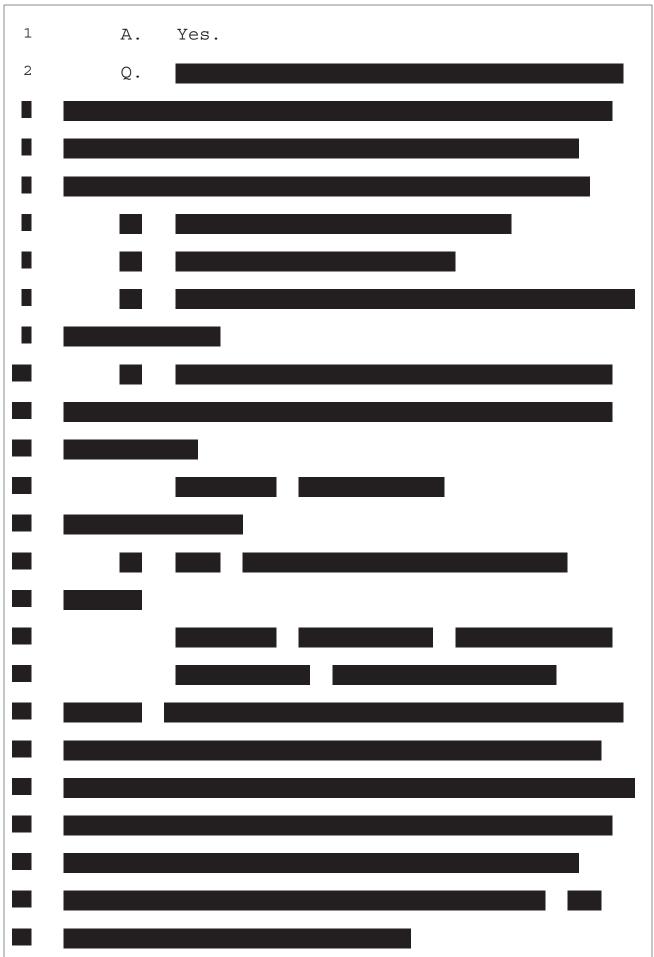


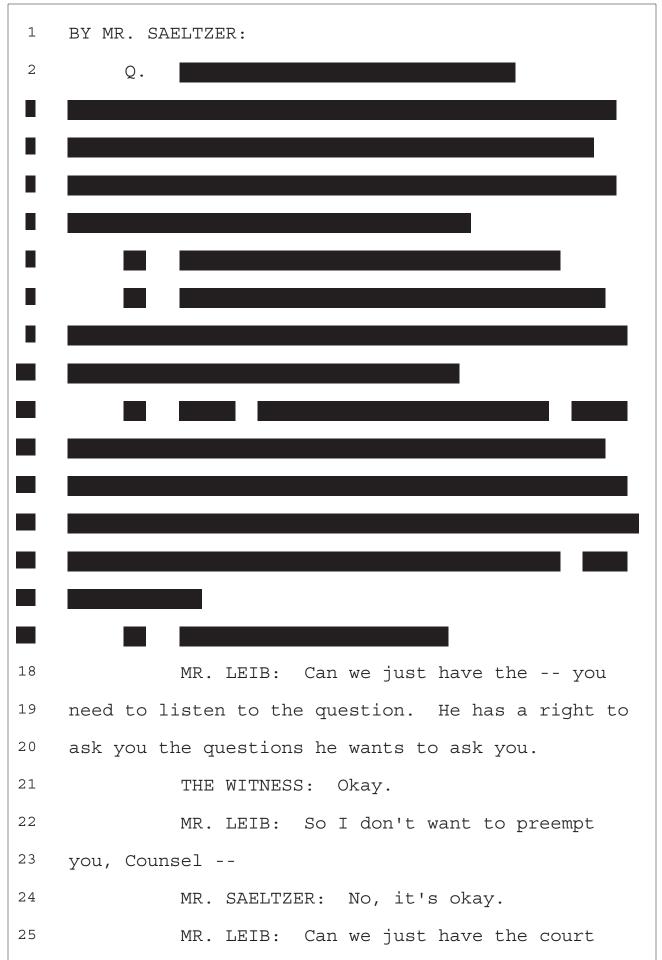
1 I -- I usually discuss the need to treat 2. the clots or the prevention of future clots. 3 with -- I usually explain to patients that the IVC 4 filter is not a cure, it's a preventative thing, 5 and that -- that medications, that blood thinners, you know, Coumadin, now Xarelto and other 6 7 medications, they -- they can help mitigate the risk of clot. 8 9 What I'm trying to learn is I take it 10 some patients cannot be put on blood thinners; is 11 that correct? 12 Α. Yeah. Some patients it would be 13 considered risky. They might have predisposing 14 conditions that would warrant maybe some caution in 15 using blood thinners. Those are the types of 16 decisions that a lot of internal medicine doctors 17 might make. 18 Ο. 20 Α. 25 Q.

- 1 5 I might have a -- an opinion, as might Α. the internal medicine doctor. It's a team effort, 6 7 and it's usually a consensus opinion. 8 One of the things the team would talk about in a clinical setting like this is whether or 10 not pulmonary embolism, deep vein thrombosis, one of the discussions typically would include whether 11 12 or not the patient could tolerate blood thinners? 13 MR. LEIB: I'm sorry, I lost the question 14 with the door slamming. Sorry. Could you read 15 that back? MR. SAELTZER: We had the wind close the 16 17 door at an inopportune time. 18 COURT REPORTER: "One of the things the 19 team would talk about in a clinical setting like 20 this is whether or not pulmonary embolism, deep 21 vein thrombosis, one of the discussions typically 22 would include whether or not the patient could 23 tolerate blood thinners?" 24 BY MR. SAELTZER: 25 O. Do you understand my question, Doctor,
- Golkow Technologies, Inc.

1 or --2. Α. Yes. 3 MR. LEIB: 5 BY MR. SAELTZER: 6 0. Yes, although I'm pretty confident that 7 time period wouldn't have changed the practice. Yes. 8 Α. 9 Okay. Because there's different methods 10 of treating a patient at risk of pulmonary embolism 11 that would include IVC filters and medications? 12 Α. Yes. 13 And as a team, you work together to come 14 to a treatment plan that is believed to best suit 15 the patient? 16 Α. Yes. 17 So here, based on that team approach and 18 the information you had, it was felt that even 19 though the patient could be placed on medications, 20 there would be an additional benefit in having an 21 IVC filter placed? 22 Α. Yes. 23 Q.

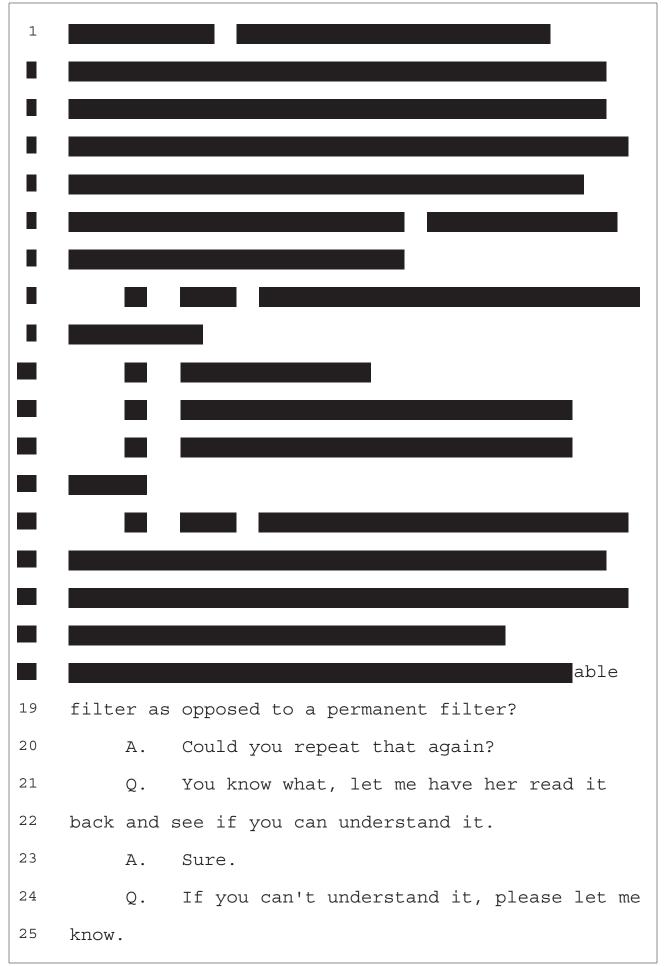


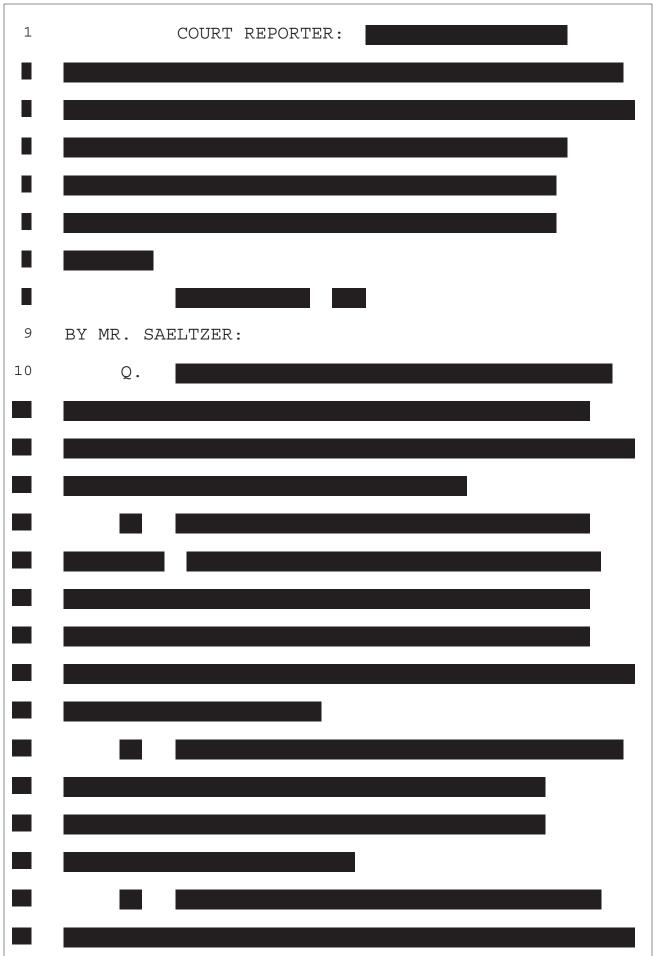


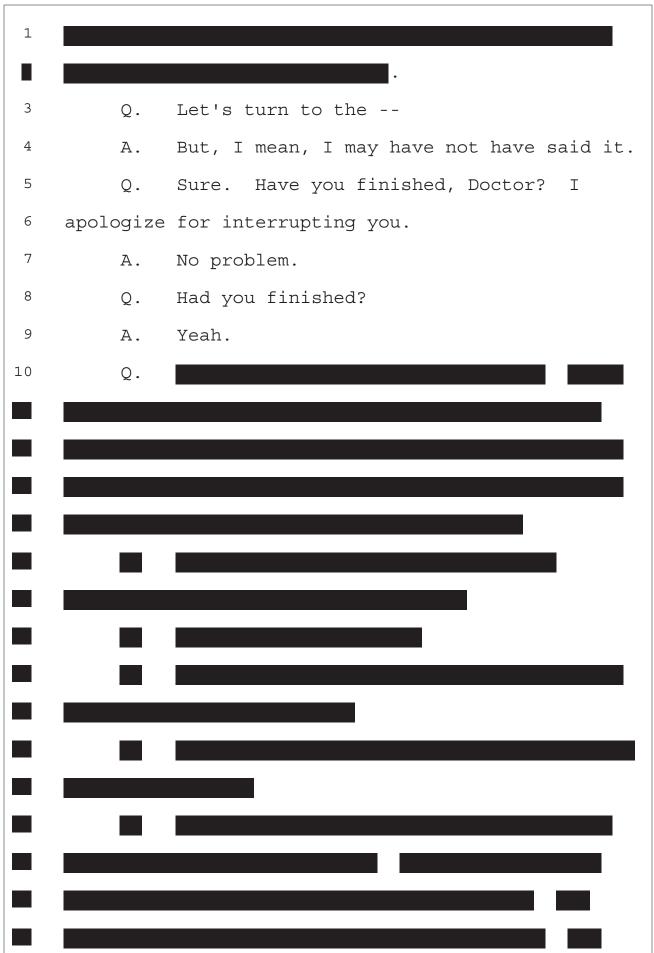


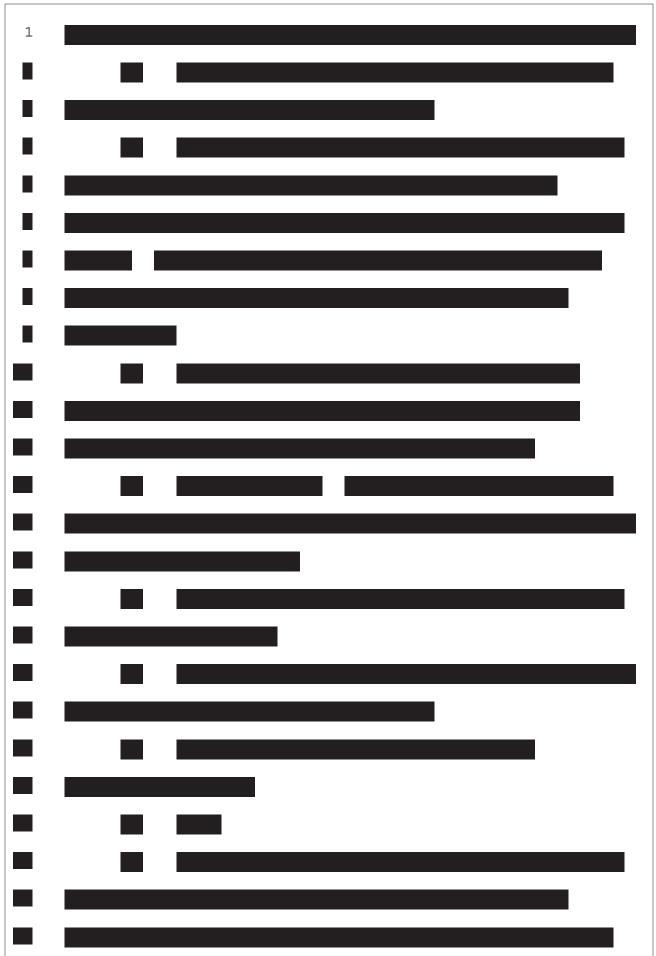
reporter read back the question. And listen and 1 see if you can answer it. And if you can't, you 2 3 say you can't. BY MR. SAELTZER: 4 5 Q.

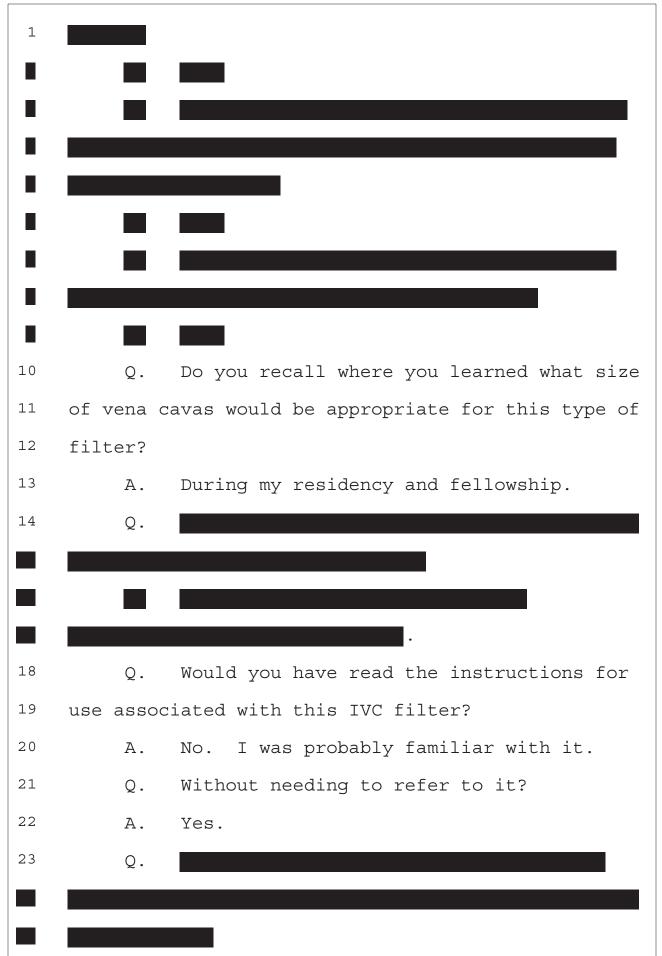


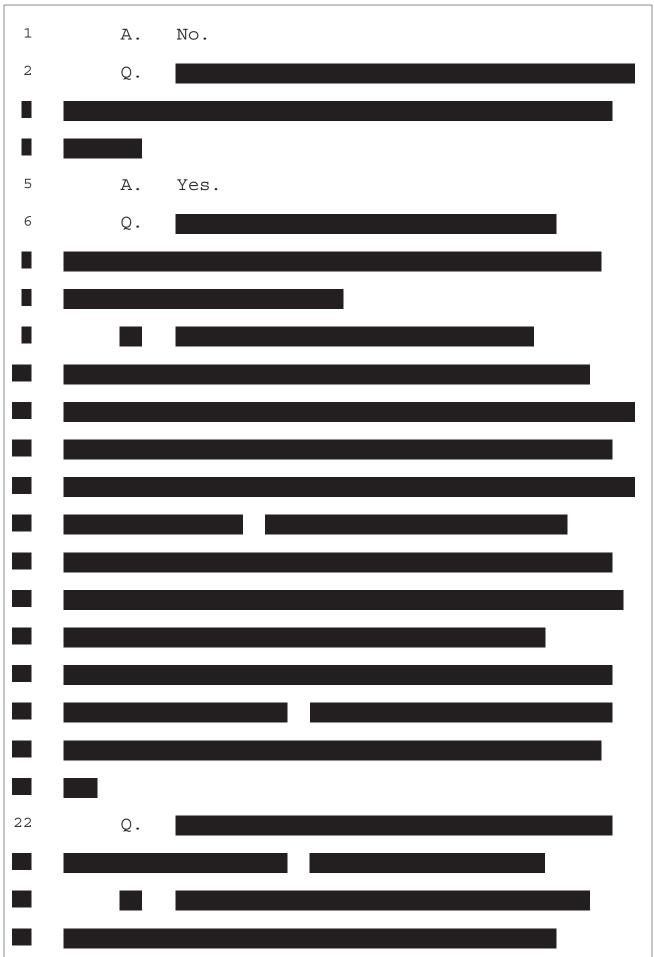
















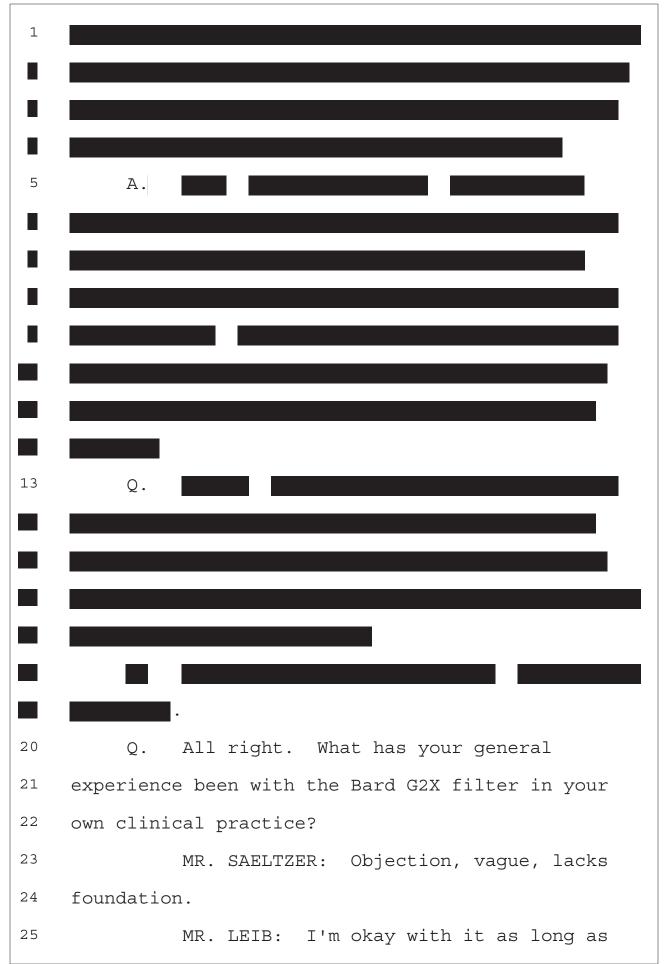
1 Α. 9 MR. SAELTZER: Doctor, at this time I'll 10 pass questions. Thank you for sitting through my 11 questions today and answering them. I may have 12 some follow-up. But at this time, I'll pass 13 questions to Ms. Daly. 14 MS. DALY: Thank you very much. 15 EXAMINATION 16 BY MS. DALY: 17 Dr. Henry, I'm going to skip around a 18 little bit just to fill in some holes that I have. So if you bear with me while I skip around. 19 20 Following up on that last question that you were 21 asked. At the time that you , I think you've testified that 23 you were aware that complications with filters included movement of the filter, fracture, and even 24 25 embolization or movement of a fractured fragment;

- 1 is that true?
- 2 A. Yes.
- Q. Did you ever have an opportunity to read
- 4 the instructions for use document that accompanied
- 5 the
- ?
- 7 A. Yes.
- Q. Are you aware that the IFU, or the
- 9 instructions for use for that filter, lists, among
- 10 the complications that -- that may occur, fracture,
- movement, and perforation of the filter?
- 12 A. Could you repeat the first part of the
- 13 question? Am I --
- Q. Yes. Are you aware that the instructions
- for use includes a section on complications that
- one might experience with a Bard G2X filter?
- 17 A. Yes.
- Q. And that that -- those precautions
- included what we just talked about with
- 20 complications, which would be fracture, movement of
- the filter, embolization of filter fragment pieces?
- 22 A. Yes.
- Q. And also that the filter can perforate;
- 24 correct?
- MR. LEIB: The question is --

- 1 THE WITNESS: Oh.
- MR. LEIB: -- whether the instructions --
- 3 the question is whether or not the instructions
- 4 state that or whether or not he was aware of that
- 5 as ? I'm sorry, I lost the question.
- 6 BY MS. DALY:
- 7 Q. Whether he believed it was within the
- 8 instructions for use precaution.
- 9 MR. LEIB: If you know.
- 10 THE WITNESS: I believe it was.
- 11 BY MS. DALY:
- Q. All right. Thank you. Has any
- manufacturer of an IVC filter provided you with any
- information, over time, that showed alleged
- 15 comparative rates of complications among IVC filter
- 16 models on the market?
- 17 A. Probably.
- Q. Do you recall any particular filter
- 19 product that that was done for -- done with?
- A. I do not recall.
- Q. Do you know if the FDA has any
- limitations or restrictions on what a filter
- manufacturer may provide by way of information
- 24 about complications to doctors?
- MR. LEIB: Well, I think maybe that's

- 1 calling for an expert opinion, but I think if you
- 2 rephrase it as of when he did this care and
- treatment, was he aware of that, then I wouldn't
- 4 have a problem with the question.
- 5 THE WITNESS: I don't specifically --
- 6 MS. DALY: Let me --
- 7 THE WITNESS: I don't --
- 8 BY MS. DALY:
- 9 Q. Let me go ahead and rephrase it, Doctor,
- 10 to cure that.
- , what
- 12 limitations or restrictions, if any, the FDA had on
- information a filter manufacturer can provide to
- 14 doctors?
- 15 A. No.
- Q. And you were asked about the type of
- 17 regulatory process that Bard filters go through,
- and the 510(k) process was mentioned to you by
- 19 plaintiff's counsel; do you recall?
- 20 A. Yeah, that happened within the last hour.
- Q. Okay. Do you have any information, or
- 22 did you -- let me put it this way. Did you have
- any information, at the time that
- , about what those regulations
- under 510(k) process required Bard to provide to

- 1 the FDA?
- A. I don't know.
- Q. So with respect to how rigorous a process
- 4 that is, you don't know what that would be;
- 5 correct?
- 6 A. Correct.
- 7 Q. When you
- , did you yourself have any expectation of
- 9 whether that filter would definitely be permanent
- or whether it might be retrieved at some point?
- 11 A. I would say that the patient's health
- care is a dynamic thing, and a patient that's had a
- couple of episodes of clots and pulmonary emboli,
- that the decision about whether it should stay or
- be retrieved, it's hard to speculate whether and
- under what circumstances that the filter may no
- 17 longer be necessary.
- And it's hard to prejudge the
- 19 situation, and so I can't speculate. But now that
- I understand the record -- and I don't know what's
- 21 happened with this patient, but I think it would be
- reasonable to get a hematologist or somebody else
- 23 stating that it's no longer needed rather than me
- try to speculate on whether it was or wasn't.
- Q. Is it fair to say then that at the time



1 it's prior , your care and treatment of the 2 patient. 3 BY MS. DALY: 4 Q. Yes. 5 My gut feeling is is that the -- the filter is widely used, that it has a good track 6 record, that it does provide protection. 7 8 that it has a good track record. I was familiar with deploying it and retrieving it. And I don't 10 know any specific numbers, but I felt it served its 11 purpose. 12 Q. Right. 17 Α. Correct. 18 Q. 22 You were asked by plaintiff's counsel 23 about several Bard documents or alleged statements where knowledge of Bard at different times. Do you 24 recall some of those questions? 25

1 Α. Yes. And many of the questions that you were Q. asked today related to the Bard Recovery filter; do 3 you recall that? 4 5 Α. Yes. 6 Q. 22 Hold on, hold on. MR. LEIB: Are we right on that? 23 24 MS. DALY: Okay. I'm not going to be having him 25 MR. LEIB:

- answer any questions, it's privileged. He'd be
- 2 having to use his expert opinion as to whether --
- MS. DALY: That's fair enough.
- 4 MR. LEIB: Yeah.
- 5 MS. DALY: That's fair enough. We can
- 6 establish it was a G2X. I don't need to trouble
- 7 him with that.
- MR. LEIB: Okay. Thank you.
- 9 BY MS. DALY:
- Q. With respect to the internal Bard
- documents that you were asked about today,
- 12 Dr. Henry, would you agree with me that you don't
- have any information about the accuracy of the
- 14 statements that Mr. Saeltzer made about Bard's
- 15 knowledge?
- MR. SAELTZER: I'm just going to object.
- 17 If that's going to be a credibility issue, then
- 18 that opens the door for me showing the documents.
- Just because we can't use documents doesn't mean
- 20 someone can get --
- 21 BY MS. DALY:
- Q. Let me ask it a different way.
- Dr. Henry, do you have any particular knowledge of
- internal Bard processes or documents?
- A. No, I don't.

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1
              MS. DALY: Let me just whip through my
    notes really quickly, but I think I'm ready to turn
 2
    you over -- back over to Mr. Saeltzer. Just one
 3
 4
    second.
 5
                  (Pause in the proceedings.)
              MS. DALY: Yes, I'll turn the witness
 6
 7
    over.
 8
              MR. SAELTZER: I don't have any further
9
    questions. Do you need more time to review your
10
    notes, Counsel? Otherwise, I think we're done.
11
              MS. DALY: No, I'm good. Thank you very
12
    much.
13
              MR. SAELTZER: Thank you, Doctor.
14
              MR. LEIB: Okay.
15
              THE VIDEOGRAPHER: Going off the record
    at 12:28. End of deposition. Media two of two.
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         STATE OF WISCONSIN
                              )
                                 SS.
 2
         COUNTY OF MILWAUKEE )
             I, ANITA KORNBURGER-FOSS, Registered
 4
         Professional Reporter and Notary Public in and
         for the State of Wisconsin, do hereby certify
 5
 6
         that the preceding deposition was recorded by
 7
        me and reduced to writing under my personal
         direction.
 8
 9
             I further certify that said deposition was
10
         taken at 2040 Airport Drive, Milwaukee,
11
        Wisconsin, on April , 2017, commencing at 10:09
12
         a.m. and concluding at 2:15 p.m.
13
             I further certify that I am not a relative
14
        or employee or attorney or counsel of any of
15
         the parties, or a relative or employee of such
16
         attorney or counsel, or financially interested
17
        directly or indirectly in this action.
18
             In witness whereof, I have hereunto set my
19
        hand and affixed my seal of office at
20
        Milwaukee, Wisconsin, this 5th day of April,
21
         2017.
22
       ANITA KORNBURGER-FOSS, RPR - Notary Public
23
    My commission expires May 13, 2017.
24
25
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